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Mechanical properties of polymeric packaging films after radiation sterilization

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MECHANICAL PROPERTIES OF POLYMERIC PACKAGING FILMS AFTER RADIATION STERILIZATION

By

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

The use of radiation as a sterilization process is increasing. The well-developed technology of the radiation sterilization as applied to medical devices has assured the food industry that the process is reliable. Due to the food industry's possibility of widespread use, it is especially crucial that an appropriate packaging material be chosen so that its integrity is maintained after irradiation. This is because the commercial food packaging process carries products through more rigorous paths and channels than medical supplies.

Many polymers used in the medical field show various degrees of degradation after radiation exposure, which can be determined either by visual or physical measurement. This paper studies the mechanical properties of polymeric films after irradiation doses of less than 10.0 Mrads and the extent to which this process causes film degradation. In this study, two mechanical properties will be measured: tensile strength and percentage elongation at break. Eight polymeric films commonly used in the food packaging industry are selected as the material samples. These materials will be irradiated with doses of 2.5, 5.0, 7.0, and 10.0 Mrads to determine cause-effect and dose related effect.

Data collected for tensile strength and percentage elongation at break for each sample of one type of film before and after irradiation is analyzed and compared with data collected for other samples. Two primary purposes in undertaking this analysis are (1) to determine if the type of film significantly changes or degrades after irradiation, and (2) to study the relationship between the changes in mechanical properties of each film and the radiation doses of 0.0, 2.5, 5.0, 7.0, and 10.0 Mrads.

In the analysis at 0.05 level of significance, polyethylene film (TD-transverse direction) is the only film which did not significantly change in either tensile strength or percentage elongation at break. The polyester/polyethylene film (MD-machine direction) significantly changed in percentage elongation at break although not in tensile strength. The rest of the film samples -PP, OPP, PETG, Polyester/PE(TD), polyester-MYLAR, PE(MD), PE/Nylon and PS film- exhibited significant changes in both mechanical properties after irradiation with doses of 2.5, 5.0, 7.0, and 10.0 Mrads.

In the analysis of the degree of relationship between mechanical properties of each film and radiation doses of less than 10.0 Mrads [0.0 (non-irradiated), 2.5, 5.0, 7.0, and10.0 Mrads] found in this study can be catagorized into three types: the dose-dependent, the dose-independent, and the weak correlation.

Among three film samples which exhibited the "dose-dependent" relationship, only oriented polypropylene(OPP) film was found to have the correlation between mechanical properties (both tensile strength and percentage elongation at break) and radiation doses; both mechanical properties decreased as the dose increased. Polypropylene (PP) was determined to exhibit the same correlation but only between tensile strength and radiation dose. For polyethylene (machine direction only), this correlation was found only for percentage elongation at break and radiation dose.

The rest of the film samples were found to have no correlation between either mechanical property and radiation doses such as that indicated above. They are either "dose-independent" or exhibit a weak relationship between the two variables. For example, the polyester-MYLAR film exhibited obvious "dose-independent" characteristics since both mechanical properties increased significantly from 0.0 to 5.0 Mrads and then decreased at 7.0 Mrads. The films which obviously showed a very weak relationship between the mechanical properties and the radiation doses are two films which exhibited no change in mechanical properties after irradiation in the first study [PE(TD-tensile & percentage elongation) and polyester/PE (MD- percentage elongation)]. The films which exhibited a somewhat weak relationship between the two variables are PS (MD&TD- tensile & percentage elongation) and PE (MD-tensile). These last two films also showed a very small change in the mechanical properties after irradiation although not as small as the films irradiated in the first study.

Chapter I
INTRODUCTION

INCREASING USE OF RADIATION

Over the past few years, the use of radiation sources for industrial application has been widespread. Worldwide sales of radiation processed products have been expanding steadily at a rate of approximately 25 per cent per annum.[1] Three well-established technologies radiation cross-linking, radiation curing of coatings, and radiation sterilization - now represent large-scale commercial applications. The radiation processing with the highest market value is the irradiation of cross-linked cables, wire, plastic-tubing or rubber material, and radiation for curing and coating. The cross-link method is used on a material to improve its properties: for example, to upgrade the electrical insulating property of cable and wire as well as to improve the performance of the rubber used for automobile tires. The simplicity of the radiation cross-link treatment replaces the conventional chemical methods which entail difficult, complex and more costly procedures. The radiation curing of inks, coatings and adhesives during the manufacturing of a wide range of products constitutes another success. This is because this technology offers ease of operation, cleanliness, and moderate cost.

The radiation sterilization of medical supplies is a well-established technology having a very large volume and is second to radiation processing with regard to market value.[2] Economy, better control and increased flexibility of the process make its use widely accepted. The product user gains benefits such as complete sterilization. While ethylene oxide (EtO) gas and steam can effectively kill micro-organisms that exist on the surface of the product, the gamma rays can penetrate and sterilize every portion of the product and its package. Also, radiation sterilization leaves no residue and imparts no radioactivity since it utilizes pure energy, similar in many ways to microwaves and x-rays. [3]

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[1]Adolphe Chapiro, " A Worldwide View of Radiation Processing, "Radiation Physic Chemistry, Vol. 22, No 1/2, 1983., p.7.

[2]Ibid., p.10.

[3]See Appendix A: Comparison of Sterilization Methods.

The up-and-coming industry of food preservation, which benefits from radiation sterilization, is also enjoying significant progress. The United States is now starting its fourth decade in food irradiation research. Radiation has been the preservation method applied to commercial food to prolong shelf life, eliminate harmful organisms, and reduce spoilage. The advantage over conventional methods is that the food products remain safe and wholesome. With regard to international development, developing countries' food industries receive many benefits through radiation processing. The radiation processing of food offers a wide range of applications which reduce post-harvest losses of food and increase food availability to their population. It provides more and better quality foods at reasonable cost when compared with the cost of conventional methods such as heat or sub-zero refrigeration treatment.[1] This application can make a direct contribution to improving the nutrition and health of populations in developing countries.

HOW RADIATION WORKS

Radiation itself is a broad, catch-all term which describes energy in movement. Radiation in all its forms is simply the transportation of energy without the participation of a material medium. In fact, a medium usually is a powerful obstacle.[2] Two forms of radiation capable of killing bacteria are:

a. Non-ionizing radiation. There are two types of non-ionizing radiation, infra-red and ultra-violet. Infra-red is a highly penetrating type of radiation which induces a rise in temperature in whatever material is exposed to it. Infra-red is used for therapeutic purposes, using suitable lamps, and for cooking in ovens. Ultra-violet radiation can also be produced from suitable lamps, has low penetrating power and is suitable only for the sterilization of contaminated surfaces and for minimizing the bacterial population of cabinets and rooms in which aseptic processes are conducted.[3]

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[1] P. Loaharanu, " Benefits of Radiation Processing to Food Industries in Developing Countries," Radiation Physic Chemistry, Vol.22, No.1/2, 1983, p.229.

[2] Jim Wagner and Marc Sillard, " Pasteurizing with Electrons," Food Engineering International , March 1989, p. 41.

[3] C.F. Ross, Packaging of Pharmaceuticals Products, Sterilization and Safety , (Tonbridge, England: The Whitefriars Press, 1983), p. 33.

b. Ionizing radiation. This is the radiation type approved by FDA for food irradiation sterilization. Because of its destructive effect upon the contents of living cells, ionizing radiation is lethal to micro-organisms.

For ionizing radiation, energy is carried two ways. Electromagnetic quanta-photons are one carrier. Gamma rays are an example. Atomic particles such as electrons are another. When these carriers strike a material, they are partially or completely absorbed. Because of this trait, radiation is said to interact with matter. If the carrier strikes matter with enough force to free an electron, the process is called " ionization," and the subsequent radiation is called " ionizing radiation."[1]

The use of ionizing radiation to kill microorganisms has been known since 1943.[2] Many experiments were done to apply the technique to the commercial realm. The gamma ray from a cobalt-60 or casium-135 source, and electron radiation from a linear accelerator electron source, are known as food irradiation sources.[3] The sterilization effects occur when the accelerated electrons strike a cell and transfer their kinetic energy, resulting in the activation of water molecules. The products of these broken down molecules inactivate the enzyme system in both the food and its microbial contaminants.[4] The disruption of the DNA molecule results in the prevention of cellular division and consequently prevents the propagation of biological life.[5] The specific dose used to irradiate food depends upon the objective of the process.

Because radiation has the same preservation effect on food as heat treatment but, unlike heat treatment, does not raise the temperature of the food. Thus, radiation sterilization has advantages over the heat process in that it retains the nutrients in the food and allows greater ease in the treatment process. The practical benefits are summarized as follows :

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[1]Jim Wagner and Marc Sillard, " Pasteurizing with Electrons," p. 41

[2]Martin A. Welt, " Status of Commercial Food Irradiation in the United States," Radiation Physic Chemistry ,Vol 22, No.1/2, 1983., p 215.

[3]See Appendix B: Figure 3. Typical Radiation Sterilizer.

[4]Rasetta L. Newsome,ed., " Perspective on Food Irradiation," Food Technology , February 1987, p.100.

[5]Radiation Sterilizers Incorporated, "What is Radiation Sterilization?," RSI Gammagram (Illinois : Radiation Sterilizers Incorporated, 1988), p.1.

1. Improvement of Public Health Standards

a. Destruction of Pathogens

Low dose radiation of 0.25 - 0.5 Mrad.(2.5-5.0kGy.) can eliminate many pathogens and parasites which are associated with food, such as Salmonella, T. spiralis T. solium, etc. The USDA is interested in using food irradiation to control disease-causing microbes, thereby ensuring that food products are safe and wholesome. Irradiation is an excellent tool for controlling salmonella and other foodborne pathogens. Radiation doses of about 0.25 Mrad would eliminate most of the pathogens on fresh meat and chicken, so the pathogens would take much longer to multiply to potentially harmful levels.[1] The treatment ensures safety of consumption.

b. Reduction of Chemical Residue in Food

Irradiation offers an excellent alternative to chemical fumigation. Many food products are fumigated against insects and microorganisms. Traditional treatments, such as ethylene dibromide fumigation, leave undesirable residues in food.[2]

c. Extension of Shelf Life of Food

- Irradiation at a low dose 0.01 Mrad. will help inhibit sprouting of root crops, such as potatoes, onions, yams, etc., for several months or over the entire season.

The proper irradiation treatment alone or irradiation plus above-zero refrigerated storage helps extend the shelf life of food. A radiation dose of approximately 0.3 -0.5 Mrad. would double or triple the shelf life of fresh poultry and meat products at normal storage temperatures (i.e. refrigerated).[3]

2. Low Energy Requirement

When irradiation is compared with heat or sub-zero refrigeration treatments, less energy is required when heat sterilization is replaced with radiation treatment in the aseptic process.

In some cases, irradiation can be combined with heat or above zero refrigeration to achieve better food quality at an energy requirement less than that used for heating or refrigeration alone.

3. High Capital Costs, but Low Operating Cost

The irradiation technique has high capital costs and requires a critical minimum capacity

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[1]Pamela Zurer, " Food Irradiation, A Technology at A Turning Point," C&EN , May 5, 1986, p. 52.

[2]See p. 1.

[3]Loaharanu, " Benefits of Radiation in Developing Countries," p.229.

for the economic operation of the radiation facility. But the difference from other physical processes is the low operating cost. In the aseptic process, if irradiation replaces hydrogen peroxide (H_2O_2), it will help save a lot of the money which would be spent monitoring H_2O_2 sterilization.

4. Insect Disinfestation

Dry food, spices, fruit and wheat are examples of foods which are irradiated for purposes of insect disinfestation. According to the report on the irradiation treatment on 5-day -old Dacus dorsalis larvae, 0.015 Mrad. irradiation can achieve better than the prohibited 9 level of mortality, based on the criterion of efficacy of non-emergence of adult insects.[1] Irradiation treatment provides greater benefit over former insect disinfestation methods. Irradiation is clean and does not leave any residue as does ethylene dibromide fumigation. The method can be an alternative to the hot water treatment which decreases the quality of the fruit. Since EDB was banned in 1984, Hawaiian papaya must be immersed twice in hot water to kill off all fruit fly eggs. The fruit, in turn, absorbs too much heat. The enzymes responsible for ripening are inactivated and the papaya never ripens properly. This experience has made papaya growers become interested in the irradiation method.[2] In fact, not all fruits take well to radiation. Avocados, pears and cantaloupes can suffer a loss of quality. However, bananas, mangoes, papayas, cherries, apricots, strawberries and figs are good candidates for the process.

The irradiation process, unlike chemical fumigation, is not essentially a batch treatment. Irradiation, instead, provides continuous treatment which would save time and money without leaving any residue.

ADOPTION OF IRRADIATION TECHNOLOGY THROUGHOUT THE WORLD

The irradiation process has been used for many years in countries other than the U.S. In the U.S., indepth food irradiation studies began in the early 1950's. Many advantages were discovered about the technique, such as that it leaves no residue and that it does not make the food radioactive. However, the fact that radiation does cause small chemical changes in food,

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[1]Chamlong Chettanachitara, "Post Harvest Entomology," paper presented at the Improvement of Postharvest Handling System for Fresh Fruit and Vegetables Symposium, Department of Agriculture, Bangkok, September 30, 1988, p. 6.

[2]Zurer, " Food Irradiation," C&EN, May 5, 1986, p. 56.

resulting in radiolytic products, raises the question as to whether the food is safe for consumption.

While food irradiation research expanded, there was an increasing emphasis on finding the right packaging for radiation sterilized food, in order to launch the irradiated food into commercial use. "Safe for use after radiation" is a primary criterion for packaging materials proposed for use in radiation preserved food. Attention focused upon the possibility that the food could become contaminated by the release of chemicals from the irradiated plastic film that packaged it.

The "new era" for food irradiation in the U.S. began in 1980. One of the significant events was when the use of ethylene dibromide as a fruit fumigant was banned in 1982. This ban caused FDA to allow irradiation to replace gas treatment. After the emergency approval was granted, there was much effort to permit radiation on food intended for commercial use. This is because, after 30 years of research, the Council for Agricultural Science and Technology reported that they had failed to find in irradiated food, radiolytic compounds that are not found normally in any untreated food or in foods treated with other accepted methods of food processing.[1] Actually, at radiation doses of less than 0.1 Mrad., the FDA committee found the quantities of unique radiolytic products in irradiated foods to be so small (on the order of parts per billion) that they were very difficult to detect and thus determined to be toxicologically insignificant.[2] Radiolytic products are compounds that the radiation creates in food. When food is irradiated, the primary chemical reaction is the breaking down of water into hydrogen and hydroxyl radical and hydrated electrons. (Fruits and vegetables, for example, contain up to 80% water.) These radicals recombine to form water or hydrogen peroxide. The primary radicals also can react with the other components of food to yield secondary radicals. For example, the peptide chain may be hydrolyzed or agglomerated by crosslinking. People eating irradiated foods would consume only a few micrograms a day of radiolytic products of any kind. In contrast, each day we take in 3 to 4 g. of chemical food additives, many of which have never been tested but are assumed to be safe.[3]

Significant progress can be seen regarding the difference between the first FDA approval for the use of radiation on food to disinfest wheat in 1963, and the 1986 FDA approval.

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[1]Newsome, " Perspective on Food Irradiation." p.100.

[2]Zurer, " Food Irradiation," C&EN, May 5, 1986, p. 49.

[3]Ibid.

In 1986, more food groups were permited to be irradiated with higher doses and with more confidence about the wholesomeness of the food.[1]

In 1986, FDA approved irradiation for	dose
-potatos, onions (to inhibit sprouting)	0.3-0.4 Mrad
-sterilizing food for astronauts and for hospital patients with immune system disorders	
-fruits & vegetables (to disinfest and preserve)	0.3- 1 Mrad
-fresh pork (to control the parasite, trichinella spiralis)	
-spices and herbs (to control insects through disinfestation)	1- 3 Mrad
-dehydrated food	

THE NEED TO STUDY PLASTIC PACKAGING MATERIAL

Ionizing radiation has been used in the production of plastic films for over three decades, to impart desired physio-chemical properties to the film during the manufacturing. In recent years, since the use of radiation to preserve fresh meat, pork and other food products has already been approved in the U.S., radiation has been increasingly used during or following the packing and packaging steps.[2] This is because, in the food irradiation process, one major concern is food born disease.

In the commercial food irradiation process, plastic packaging films are irradiated either purposefully or incidentally along the packing or packaging line.[3] Plastic films irradiated purposefully denotes, for instance, the process whereby the irradiation pre-sterilizes films prior to filling and sealing in aseptic packaging, or the irradiation sterilize the bulk of the plastic pouch and other preformed packages. Plastic films irradiated incidentally denotes, for instance, the process whereby the sealed plastic pouch containing food is irradiated in order to achieve pasteurization or sterilization of the food.

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[1]See Appendix C: List of Clearances (As of March 22, 1988.)

[2]George G. Gidding, " Irradiation of Packaging Materials and Prepackaged Foods, " Journal of Plastic Film Sheeting, Vol 2, No. 1, 1 Jan 1986, p. 75.

[3]Zurer, " Food Irradiation," C&EN, May 5, 1986, p. 51.

STATEMENT OF THE PROBLEM:

THE NEED FOR A MECHANICAL PROPERTIES STUDY OF THE PLASTIC FILMS USED IN COMMERCIAL IRRADIATED FOOD PACKAGING.

Packaging constituted an essential step in moving irradiated food into commercial use since the era of irradiated food began. Most of the research was concerned primarily with residues which could migrate from the packaging material to the food product after radiation.[1] This emphasis is the case with the Killoran report.[2] In three specific areas of his research, the first two topics concern the extractive and the volatile substances issuing from irradiated plastic film, and the last topic is about the changes in mechanical properties. There are more studies on packaging and product compatibility probably because the question as to how safe the material was for use was considered to be more significant and thus made it more difficult to make any decision. Since irradiation was not widely used because approval had not been granted, there had been no feedback from which to confidently draw conclusions. Also, due to the lack of commercial use, the information on the mechanical strength of the material functioning as a container was not sought at that time.

After a long period of study, the United States is now commencing its fourth decade in food irradiation research.[3] Much research has been done on the commercial practice of irradiation, and packaging has become the main focus for the step of bringing the technique into the marketplace. Earlier research on the material components of polymeric materials and their safety for use as irradiated food packaging is now available.[4] Additional work remains to be done on the physical properties of the plastic packaging. Strength of packaging is essential so as to contain and move the product through the radiation processing and distribution channels, and to protect the product from recontamination after irradiation. Indeed, much work has already been

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[1]See Chapter II, section entitled "Irradiated Packaging Material Testing Report"

[2]John J. Killoran, " Chemical and Physical Changes in Food Packaging Materials Exposed to Ionizing Radiation," Radiation Research Reviews, v. 3,1972, p. 369.

[3]Welt, "Status of Commercial Food Irradiation in the United States," p. 215.

[4]See Appendix D: FDA Approved Polymeric Films: CFR 179.45.

performed by the medical device and pharmaceutical industries. However, most of the information was case specific and proprietary to the individual companies, and therefore not really available for general distribution.[1]

PURPOSE OF THE THESIS

After the long period of experimentation, the results derived from studying the mechanical properties of packaging material after irradiation have been reported in various forms. The goal of this thesis is to perform the basic physical tests on irradiated packaging films, gather data, and put the results into a standard format which could be a beneficial reference for packaging personnel.

Two aspects of the data and results will be studied:

1. Whether or not there are any changes in mechanical properties of plastic packaging films after irradiation.
2. The relationship between radiation doses and effects.

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[1] Fritz Yambrach, "Comments at the Irradiation Food Product Committee Meeting, the 41st Annual Meeting of R&DA at the Omni International Hotel & Norfolk Naval Base, Norfolk, V.A. 5-7 May 1987," Minutes of Committees and Subcommittees of the R&D Associates, (Texas: Research and Development Associates for Military Food and Packaging Systems, Inc.) Spring 1987, No.4, p.34.

Chapter II
REVIEW OF LITERATURE

THE IONIZING TREATMENT FACILITY

Ionizing radiation is lethal to micro-organisms because of its destructive effect upon the contents of living cells. According to the proposed FDA regulation (21 CFR, Part 179) which is listed specifically under paragraph 179.26, the approved energy sources are:

1. Gamma rays from sealed units of the radionuclides Cobalt-60 or Cesium-137.
2. Electrons generated from machine sources operated at energy levels not to exceed 10 million electron volts (MeV).
3. X-rays generated from machine sources operated at energy levels not to exceed 5 million electron volts.

Cessium 137 emits its energy at 0.60 MeV and has a half-life of 30 years. Cobalt-60 emits at two energy levels, respectively 1.173 and 1.33 MeV and its half-life is 5.3 years. Electrons can be produced in a very narrow energy band as specified by the operator and consistent with the allowable upper limit of 10 MeV. X-Ray photons will have a broad energy spectrum ranging from zero to an upper level equal to the energy of the electron beam producing it, and so far specified by pending or existing regulations as 5 MeV.[1]

Of these, there are two methods which are effective and readily available commercially:

1. Gamma radiation.
2. Electron-beam radiation.

Equal doses of electron and gamma radiation have essentially equal biological effectiveness, at least in the energy range of practical interest for radiation processing. This is due to the same chain of events, leading to the transfer of energy from the incident radiation to the irradiated system and resulting in chemical changes of the components of living cells, especially of the vital DNA molecules, for both types of radiation. [2]

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[1]A. M. Rodrigues and RPC Industries, "Comparison of Machine-Generated Electrons and X-Rays in Food Irradiation." Paper Presented at the 30th Annual Atlantic Fisheries Technological Conference, Boston, Massachusetts, August 25-29,1985, p.2.

[2]L. Wiesner, "The Complementary Nature of Electron and Gamma Radiation for the Sterilization of A Wide Variety of Products," Radiation Physic Chemistry, Vol 22, No. 3-5, 1983., p.685.

1. GAMMA RADIATION

A plant using gamma radiation would comprise a radiation source, protective shielding, conveyor systems both inside and outside the radiation chamber, together with control and safety equipment.

1.1 Gamma Radiation Source

Gamma rays are the isotropic emission of radioisotope sources. Two sources for gamma radiation are Cobalt-60 and, used to a far lesser degree, Cesium-137. Both are hazardous materials and must be handled with great care. However, Cobalt-60 is recommended as it is less hazardous and more efficient since it radiates power more uniformly.[1] Cobalt-60 is a radioisotope of cobalt. It is produced by exposing Cobalt metal (Cobalt 59) to neutron fluxes in a nuclear reactor.[2] At the facility, Cobalt-60, having a specific radioactivity of more than 100 curies per gram, is assembled in the form of tiny cylinders to form rods 450 mm. long. These rods are fully screened by hermetically-welded double walls of stainless steel. A rod of Cobalt-60 usually contains 10,000 curies.[3] A number of rods are placed in a source rack. A vessel filled with water, to act as a shield against radiation, serves as a storage accommodation for the cobalt unit. When the radiation process is inoperated, the wall of rods is moved underneath the six-foot water tank. The source rack is designed to allow rods to be removed and exchanged for higher strength source rods. Some commercial units also offer dual source racks for source variability and efficiency.

1.2 Radiation Chamber

The walls of the radiation chamber are made of 1.8m-thick concrete to ensure a safe shield for the surrounding areas, which include the control room and the production hall. Safety equipment is also housed in the control room.[4] To obtain optimum utilization of the plant, a system of conveyors is selected which allow the product to be continuously supplied and discharged, 24 hours a day for seven days a week. The process is supervised by a telemetric monitoring system, and bulk goods can be handled in pallet loads in many instances.

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[1]Judy Rice, "Irradiated Packaged Foods - the Pros, the Cons, and the Prospects for Future Commercialization," Food Processing, Vol. 50, No. 6, June 1989, p.53.

[2]Ibid.

[3]Kirsten Nielson, "Use of Irradiation Technique in Food Packaging" in Modern Processing Packaging and Distribution Systems for Food, ed.G. Frank A. Paine, (New York: Van Nostrand Reinhold Company Inc.,1987,) p.55.

[4]Ibid.

1.3 Conveyor System

The conveyor system of each commercial radiation facility is designed for the purpose of insuring accurate specific doses for each product as the system moves products past the source. A monorail track and overhead rail track are set in a pattern that directs the product carrier to move around the source and to allow the front and back of the tote facing the source rack an equal amount of time. A computer is necessary for controlling programmer tracks and directing the movement of each product carrier and product totes container as it cycles through the cell within the chamber. There are some models which also offer automated handling outside the cell. The out-of-cell automated features enable the loading/unloading multi-level carrier designed to carry multiple products to receive different irradiation doses at the same time. This system was developed to make the slow process of gamma irradiation become more efficient with higher throughput.[1]

2. ELECTRON BEAM RADIATION

The electron beam irradiation facility also has a similar set-up plan to the gamma irradiation plant. There are the electron source, the conveyor, and the chamber with the control room and safety system. The major difference from the gamma irradiation facility is that electrons are produced from a machine source.

2.1 Electron Beam Source

Electron beam radiation is produced by electro-mechanical devices. Electrons are accelerated to a specified energy and are allowed to pass through a thin metal foil (window) to strike the products. Machine sources have been developed to produce electron energies of several million electron volts, but for the purpose of food irradiation, the energies used are 10 MeV or lower.[2]

For the commercial system, the major components of the source are the electron accelerator, the modulator and the scanning horn. Each individual system operated nowadays will have three main parts which differ slightly in scheme.

Modern electron beam processors are fully computer controlled. The energy and size of the radiation field can be automatically changed. By varying the scan parameters to suit the size of the packages, optimal radiation, i.e. lower max/min dose rations and minimum over

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[1]See Appendix B: Figure 4.Commercial Gamma Radiation Facility-Radiation Sterilization Inc. (RSI), U.S.A.

[2]Rodrigues, "Comparison of Machine-Generated Electrons in Food Irradiation," p.3.

scanning can be achieved. An example is the operation of the CGR-MeV system in Buc, France. The CGR-MeV system accelerates electrons and disperses them in a beam through a "scanning horn" directly above the product. The exposure time beneath the beam determines the dosage.[1] At the facility, a 3 kGy dose is effected in less than one second. The diameter of the beam is 3 cm. and its duration 220 ms. The beam is configured by the scanning hom to cover a 50 cm. area. The energy pulse is from 100-200 joules per scan, and the penetration is 45 cm. [2]

2.2 Conveyor System

The forward scattering characteristic of machine produced radiation, as compared with the isotropic emission of radioisotope sources, results in a simpler and more efficient conveyor system. Since the machines are capable of much higher dose rates than economically comparable isotope sources, the same amount of material can be processed in a much shorter time. A machine such as the CGR-MeV accelerator working at 10 kW. can irradiate a deboned poultry meat slab at a rate of three tonnes per hour at 2.5 kGy. That is enough to eradicate salmonella completely.[3]

Although high dose rate electron beam radiation has certain advantages, such as a simple conveyor system and low operating cost, one of its disadvantages is the weak penetration of its beam. The food product must be flipped upside-down to insure proper pasteurization. [4] This is done mechanically by the system equipped with the conveyor, and the food receives a dose as it returns on the conveyor.

2.3 Electron Beam Radiation Chamber

The fact that electron beam radiation is produced from the turn of a switch also means that the facility that houses a machine source is much simpler than a comparable isotope facility as there is no need for a storage pool with its attendant water de-ionizing and cooling systems.[5] Also, since most of the auxiliary equipment for a machine source can be housed in an adjacent area that only needs minimal radiation protection, the volume of the fully shielded area is much smaller than a comparable Cobalt-60 or Cesium-137 facility. All of this translates into less costly facilities and contributes to the economic advantage of the machine sources.[6]

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[1]See Appendix B: Figure 5. Commercial Electron Beam Radiation - CGR MeV, France.

[2]Sillard and Wagner, "Pasteurizing with Electrons," p.40.

[3]Ibid., p.41.

[4]Ibid., p.40.

[5]Rodrigues, "Comparison of Machine-Generated Electrons in Food Irradiation," p.3.

[6]Ibid.,p.5.

Both gamma radiation and electron beam radiation are, therefore, in principle interchangeable in application to the sterilization of medical supplies, laboratory equipment, animal feed and the treatment of food for human consumption. The choice between electron and gamma radiation can be exclusively made on the basis of the technical and economical parameters, characterizing a specific application of the irradiation process.

If, on the basis of the technical parameters, either type of radiation can be applied, then the most important determining economic factors are the average product density and the required irradiation capacity. It has been shown that powerful electron accelerators in the 3 MeV range and above make electron radiation sterilization more economical for low density products and very large irradiation capacities than other sterilization methods, except gamma irradiation.[1]

With regard to the technical parameters, the inherent difference of penetration and available dose-rate between the two types of ionizing radiation may determine the choice for a specific case. The high dose-rate with which electron irradiation is performed may be beneficial for certain properties of the irradiated material, especially if doses considerably above 10 kGy have to be applied because the short irradiation time reduces the quantity of oxygen available for reactions leading to the degradation of polymeric materials. In other applications, the vary nature of the product to be irradiated may require the high penetration of gamma rays.[2]

HOW PACKAGING MATERIALS ARE IRRADIATED DURING THE COMMERCIAL FOOD IRRADIATION PROCESS

Gamma and ionizing radiation have been used for over three decades in applications such as the production of plastic film and, recently, in the packing and packaging process. Plastic films are irradiated either purposefully or incidentally on the line in three distinct ways :

1. Purposefully, to impart physico-chemical properties to the film during manufacture.
2. Purposefully, to presanitize/presterilize the film or pouch prior to filling and sealing, e.g. as in aseptic packaging.
3. Incidentally, by the treatment of food in the package to achieve pasturization (i.e. sub-sterilization) or sterilization of the food.

For the first and second applications, food packaging materials are irradiated prior to filling and sealing. For the last application, packaging materials are irradiated along with food while on the filling and packaging line.

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[1]Wiesner, "The Complementary of Electron Radiation," p.685.

[2]Ibid.

1. IRRADIATION OF FOOD PACKAGING MATERIALS PURPOSEFULLY TO IMPART DESIRED PHYSICAL PROPERTIES

Material Functions and Effects

Recently, through proprietary research and development, most single and multi-layer polymeric packaging materials have become, or are in the process of becoming, available for food and non-food industrial and consumer products. These are formulated and exposed to ionizing energy in a controlled manner so as to impart or enhance one or more physical/functional properties.

The Application and Process

The radiation-induced cross-linking of polyolefins to impart heat-shrinkability during the manufacturing process is the oldest and most prevalent industrial application in this category. [1]

From the regulation standpoint, the FDA does not require petition for premarket approval of the use of such irradiated materials, according to the pertinent section of Title 21 of the Code of Federal Regulation (i.e., Subchapter b, parts 174 through 178), which the process generally complies with. Also, permission is granted to irradiation that is performed according to "good manufacturing practices," specifically, doses not to exceed 10 Megarads or at energies not to exceed 10 MeV with electron beam irradiation.[2]

2. IRRADIATION OF FOOD PACKAGING MATERIAL PURPOSEFULLY TO PRESANITIZE/PRESTERILIZE FILMS PRIOR TO FILLING AND SEALING

Material Functions and Effects

This method is a direct extension of the gamma sanitization/sterilization of medical devices, disposable health care products, and a growing array of industrial and consumer products. The radiation treatment of food packaging materials prior to filling and sealing may be only for the purpose of presanitization (to reduce the bioburden) or it may be for full presterilization.

The Applications and Process.

1. The largest volume application of this type is the gamma sanitization of dairy blanks (unfilled containers) prior to shipping the bulk-packed blanks to dairy product plants for filling and sealing. This is typically used for bioburden reduction to extend shelf life as opposed to

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[1]See Appendix E: Figure 6. Process for Biaxially Orienting Film of Irradiated Polyethylene.

[2]Gidding, "Irradiation of Packaging Materials" p.76.

medical-device equivalent sterility. The typical dose in the United States is 0.3 to 0.4 Megarad minimum while a typical minimum dose in use for a decade in Europe has been 0.7 Megarad. (A typical medical device sterilization minimum dose is 1.5 to 2.5 Megarads.)[1] The radiation treatment has been adopted for this application due to its advantage of being a simple and economical process (costing a fraction of a cent per blank) and a residue-free alternative to gaseous fumigation.

2. Gamma sterilization is applied to the small, single serving dispensers of cream, etc., use by airline food and fast-food take-out services. This irradiation application is operated at the final step in the container manufacturing process to enhance the shelf stability of the food.

3. Radiation is used to initially reduce the bioburden on the surfaces of containers together with the sealed bulk carton to help protect the product from recontamination during distribution and storage. These applications do not require petitioning for premarket approval.

4. Another application is aseptic packaging presterilization. Gamma and electron beam radiation have become an alternative to bulk gaseous fumigation or in-line hydrogen peroxide sterilization. In Europe, gamma sterilization is used for bulk packed liter/half-liter aseptic milk carton blanks. Also, in the United States, bulk-packed multi-gallon, institutional bag-in-box units for such products as tomato puree, catsup, fruit sauces, and concentrates are using radiation sterilization. This application happened to follow the trends set by the producers of medical devices, health care products, and spice and vegetable seasonings, and was used in order to avoid ethylene oxide fumigation. Also, radiation sterilization provides benefits for worker safety, effectiveness, flexibility and convenience, as well as its advantages over gas fumigation of being residue- and effluent-free.[2]

So far, the continuous web sterization in a form-fill-seal machine has been put into commercial practice for the manufacture of pouches or semi-rigid containers. An example of in-line radiation sterilization of aseptic packaging material is the system patented by Dr. Sam V. Nablo of Energy Science.[3]

3.1. IRRADIATION OF FOOD PACKAGING/WRAPPING MATERIAL AND /OR BULK PACKING MATERIAL INCIDENTALLY TO SUBSTERILIZE PRODUCT THEREIN

A very broad range of doses and objectives of substerilization irradiation are in this

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[1]Gidding, "Irradiation of Packaging Materials" p.77.

[2]Ibid., p.78.

[3]Ibid.

category. They include bulk packages containing potatoes, onions, garlic etc. receiving very low doses of about 10 krads to inhibit tuber sprouting, packages containing fruit irradiated to disinfest fruit flies and other insect pests at around 15-30 krads, all the way to packaging for spices and seasoning sanitized at up to three Megarads.

Material and Effects

1. Specific doses of radiation can cause amber colorations of clear glass bottles and jars for retail spice packs. Cerium-added glass can be radiation-stabilized, but this may be too costly for many foods and ingredients. However, this is not a major problem because most of the applications are at a dose level below the megarad range. Moreover, glass and polymers packages, which can pose problems for certain sterilization doses, are not effected by radiation below a Megarad.

2. The odor and/or flavor of the packaging material of a prepackaged irradiated product can be noticeable at relatively high doses (i.e. hundreds to thousands kilorads). Also, food products that are not particularly good candidates for radiation preservation in the first place (e.g. certain dairy products) yield a high degree of flavor/aroma delicacy.[1]

3. For the substerilizing combination of heat and radiation, there may be a negative impact on some physical/functional properties since radiochemical effects are usually increased by elevated temperatures. This might occur when the radiation is applied to the product and package immediately after hot filling and sealing. In this case, what needs to be taken care of are any possible undesirable secondary interplay between the warm or hot packaging material and the radiation in the context of extractables. Therefore, developers of new packaging materials which come into use with pre-packaged irradiated foods need to take the impact of process-package-product interaction into consideration.[2]

The Applications and Process

1. All kinds of prepackaging/wrapping materials on food to be substerilized could be subjected to the radiation process. These include individual fruit; shrink-wrapping materials and stretch-wraps for styrofoam or fiberboard tray-wrapped meat, poultry, and fish cuts; heat shrink vacuum bags for whole poultry as well as for red meat prime cuts.

2. They also include transparent semirigid polymeric containers for cold-cuts/luncheon meats, various pouch and bulk container materials, and, in fact, most of the packaging types of plastic film or sheeting.

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[1]Gidding, "Irradiation of Packaging Materials" p.80.

[2]Ibid., p.81.

3.2. IRRADIATION OF FOOD PACKAGING MATERIAL INCIDENTALLY TO STERILIZE PREPACKAGED FOODS

For this application, packaging is irradiated due to the complete sterilization of "hermetically" prepackaged low acidic food in order to achieve long-term (1 to 5 or more years) ambient temperature shelf stability with a twelve log cycle (i.e., "12-D") level of antibolinum.[1] The study started at the Army's Chicago Quartermaster Food & Container Institute in the early 1950's, and continued at the Army's Natick (MA) R&D Center. At first, the primary focus was the tin-plate can; the later focus was the multilayer flexible retortable pouch.

The Packaging Effect

1. Since the radiation dose is stronger than 1 Mrad, all aspects such as odor, extraction, etc. are possible and need to be tested. With regard to the tin-plate can, the aspects studied include induced radioactivity (nil), and stability of the tin plate itself and solder, inner coating enamels and end sealing compounds to degradation and release of extractives. Due to the process of sterilization, the can has to withstand doses of upward of ten megarads at the upper end of the sterilization range. Also, it has to do so at temperatures of -40°C and lower. The can proved capable of withstanding these rigors.[2]

2. The development of the multilayer flexible retortable pouch was done with flexible single-portion containers. These were tested in all aspects as was the tin-plate can. For electron radiation with a penetration limited to a few centimeters, these pouches needed to be tested to make sure they are thin enough after filling and sealing so that the overall product and package are completely sterilized.[3]

WHAT OCCURS TO POLYMERS MATERIALS AFTER EXPOSURE TO IONIZING RADIATION

THE TWO MAJOR MECHANISMS OF DEGRADATION (OR CHANGE) IN A POLYMER

Polymers, which are used to make general products or packaging materials, are organic

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[1]The process has been centered around the dose needed to reduce the numbers of viable spores from 10^{12} to 10^{0} (12-D concept where D is the dose required for 90% population reduction). The D value varies with the different food medium. Edward S. Josephson, "Food Irradiation and Sterilization," Radiation Physic Chemistry, Vol.18, No. 1-2, 1981, p.226.

[2]Gidding, "Irradiation of Packaging Materials" p.82.

[3]Ibid.

materials made up of a specific type of molecule joined together in multiply repeated (monomer) units to form a high molecular weight material (macromolecule). They may be either synthetic or natural materials. These materials are frequently separated into three types as a result of their final properties: thermoplastics, thermosets and elastomers. All three types of materials are capable of being shaped into a desired product at some stage of their processing.[1] In macromolecules, the degree of crystallinity, caused by the varying regular or completely random molecular arrangement inside, is also created by additives added for specific processing conditions or added to give particularly desirable properties to the finished product. The additives are small molecules which function in the polymer matrix as antioxidants, ultra-violet light stabilizers, plasticizers, inert fillers, processing aids, etc.[2]

Polymers vary greatly in their interaction with ionizing radiation. Also, the dose necessary to produce similar significant effects in two different polymers varies considerably. It is often difficult to predict the specific properties of a polymer resulting from ionizing radiation. Certain additives have very distinct protective action in preventing radiation damage to plastics. In some instances, these compounds are called "antirads" and frequently are materials which are also good antioxidant additives for polymers materials. The action of these additives can be that of a reactant which combines rapidly with radiation-generated free radicals in the polymer, or as primary energy absorbers themselves.[3]

Radiation generally interacts with polymers in two ways, both resulting from energy being dissipated by the radiation and causing excitation or ionization of the atoms or molecules of the material concerned. The two major mechanisms of degradation or change taking place in a polymer as it is subjected to radiation are: 1. crosslinking which results in the formation of large three-dimensional networks, and 2. chain scission occurring as a random rupturing of bonds which reduce the molecular weight of the polymer.[4]

1. Crosslinking

The basic phenomenon of radiation-induced crosslinking of linear polymers is a simple reaction which lies at the basis of many present-day industrial applications. The main observations are as follows:

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[1]W.E. Skiens, "Sterilizing Effects on Selected Polymer," Radiation Physic Chemistry, Vol. 15, 1980, p.47.

[2]Ibid.

[3]Ibid.

[4]Ibid.,p.48.

a. The degree of crosslinking is proportional to the radiation dose.

b. It depends little on the type of high-energy radiation, whether sparsely ionizing (electron, x-rays, r rays) or highly ionizing (fast protons; alphas; fast neutrons, which provide fast protons by collision).

c. It depends little on dose rate.

d. It does not require unsaturated or other more reactive groupings.

e. With some exceptions (as in polymers containing aromatics), it does not vary greatly with chemical structure.

f. It does not vary greatly with temperature.

g. The efficiency of crosslinking, represented by a G value (number of crosslinks formed per 100 eV of energy absorbed), is little influenced by molecular weight.

h. However, the G value for a polymer can be greatly changed by the presence of certain additives in relatively small concentrations, e.g. acetylene, thiourea, oxygen. (This behavior offers an important correlation with phenomena studied in radiobiology.)[1]

Since these observations are based on early experiments, as cited by physicians, they need updated research for a better explanation. This is because, although the mechanism of crosslink formation by radiation has been studied since its initial discovery, there is still no widespread agreement on its nature. Much of this work has been concerned with polyethylene which, due to its quasi-complete saturated nature, demonstrates the effects most strikingly. Besides this case, there are questions about radiation crosslinking which need conclusive answers, such as whether crosslink formation is due to the combination of two species (e.g. radicals) formed independently on adjacent molecules or whether crosslinking can occur in the crystalline phase of polyethylene.[2]

2. Degradation or Main Chain Scission

The alternative reaction to crosslinking is degradation, since the former increases average molecular weight, whereas the latter reduces it. However, these two reactions are not necessarily opposite, and both may and do occur in the same polymer, so that one can get both the formation of a three-dimensional network (theoretically of infinite molecular weight) and a reduction of overall (number) average molecular weight. Here again, the initial working hypotheses have proved of surprising validity, notably that the number of scissions is proportional to dose and that they occur at random. Hence, radiation furnishes an excellent method of

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[1]A. Charlesby, "Crosslinking and Degradation of Polymers," Radiation Physic Chemistry, Vol. 18, No. 1-2, p.60.

[2]Ibid., p.65.

providing polymer of accurately controlled weight and weight distribution, and has in fact been used for this purpose on an industrial scale. How far this technology can be advanced depends on the need for such degraded products and on the cost of reducing molecular weight to this level.[1] Here again, the occurrence of main scission in crystalline polymer, or in amorphous polymer below the glass transition, still needs to be investigated more. Also, the actual mechanism of the process, such as the magnitude of the decrease in mechanical properties of Teflon correlate to dose rate, is still by no means clear.[2]

IRRADIATED PACKAGING MATERIAL TESTING REPORT

While the phenomena of crosslinking and degradation inside molecules are not yet completely sketched out, the information on practical usage of irradiated packaging materials is beginning to become available. This is due to the need to find the right package for irradiation-sterilized food. Since alterations in molecular structures of the polymer appear as changes in the chemical and physical properties, packaging researchers performed tests to determine to what extent gamma and electron radiation at food sterilizing doses alter the chemical and physical properties of packaging material. This will help them make decisions on a package for irradiation-sterilized food which is capable of withstanding rough handling and storage and which retains its protective qualities during radiation processing and storage, without any adverse effects on the food contained therein.

1. Effect of Radiation on the Chemical Properties of Plastic Film

According to research carried on at U.S. Army Natick Laboratories, plastic packaging films were tested for the following chemical properties:[3]

1.1. Substances Migrating from Plastic Films

In this study, nine food-contacting films were used. They were films approved by the U.S. Food and Drug Administration for the packaging of non-irradiated foods and they were believed to fulfill the function requirements for packaging of irradiation-sterilized food. The test materials are formed into pouches and filled with food simulating solvents. Pouches were enclosed in paperboard folders during irradiation and handling.

The primary task was to determine the nature and amount of extractives released into the food-simulating solvents contained in the flexible packaging material subjected to 6-megarad doses of ionizing radiation. The food-simulating solvents selected for this study were distilled

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[1]Charlesby, "Crosslinking and Degradation of Polymers," p. 61.

[2]Ibid.

[3]Killoran, " Chemical and Physical Changes in Food Packaging Material."

water, 0.1 N acetic acid, and n-heptane. The nature and concentration of extractives from each irradiated flexible packaging material was determined by chemical and microanalytical techniques and compared with extractives from a sample of the same material not irradiated but held in contact with the solvent under similar conditions of storage. The film samples are:

polyethylene	polyethylene-polyiso-butylene blend
polyiminoundecyl	poly(vinyl chloride-vinyl acetate)
polyethylene terephthalate	polystyrene
plasticized polyvinyl chloride	polyiminocaproyl

For the summary of results, electron and gamma radiation of plastic films in the presence of food-simulating solvents produces the same chemical compounds but in slightly different amounts. The differences were attributed to the stability of the films with regard to their susceptibility to crosslink and/or degrade at the relatively low dose rate for gamma radiation and the relatively high dose rate for electron radiation.

Extractives were found to be chemically identical with the original unextracted films, adjuvant materials such as plasticizer or, as in the case of polyiminocaproyl, unreacted caprolactam monomer.[1]

1.2 Volatile Compounds Produced by Radiation of Plastic Films

Krasnanky and Parker performed research based on the criteria that the radiation stability of plastic films may be related to the total quantity of gaseous products evolved as a result of the ionizing radiation treatment and to detected changes in their molecular structures. Five classes of plastic films had been exposed to a dosage of six megarads of gamma radiation in a vacuum at 25°c. The ranking of the plastic films in order of decreasing radiation stability was

polyethylene terephthalate > polystyrene > polyiminoundecyl >
poly(vinylidene chloride-vinyl chloride) > polyethylene.

This study indicated that the films determined to be most stable when exposed to radiation contain a phenyl group, an amide linkage and, possibly, chlorine atoms in groups that are attached to a carbon backbone chain.[2]

As part of the research program for the selection of plastic films most suitable for prepackaged electron-radiation processed foods, Angelini determined that volatile compounds were produced by radiation of the four plastic films. The films were low-density polyethylene, high-density polyethylene, poly(vinylidene chloride-vinyl chloride) and polyiminocaproyl. The films were electron-irradiated in evacuated (10^{-3}torr) glass tubes. The volatile constituents were

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[1]Killoran, " Chemical and Physical Changes in Food Packaging Material," p.376.

[2]Ibid., p.377.

collected by the low temperature-high vacuum technique and analyzed by a cryogenically programmed gas chromatograph coupled to a rapid scanning mass spectrometer. Ninety different aliphatic hydrocarbons were produced by each polyethylene, ranging in molecular weight from 16 (CH_4) to 184 ($C_{13}H_{28}$). Based on the total amount of volatile compounds produced by the electron radiation of the four films, the order of radiation stability was polyiminocaproyl > high-density polyethylene > poly(vinylidene chloride-vinyl chloride) > low-density polyethylene.[1]

2. Effect of Radiation on the Mechanical Properties of Plastic Film.

As mentioned before, the two major mechanisms of degradation or change taking place in a polymer as it is subjected to radiation are crosslinking and chain scission. As a result of chain scission, chain length decrease, causing tensile and flexural strength decrease.[2] Also, every low molecular weight fragments, gas evolution and unsaturation may occur.[3] Crosslinking generally results in increased tensile strength, while impact strength, elongation, crystallinity, and solubility decreases, and the polymer becomes increasingly brittle with increased doses.[4] For polymers with carbon-carbon chains or backbones, it is observed that crosslinking generally will occur if the carbons have one or more hydrogens attached to them, whereas scission occurs at tetra substituted carbons. Polymers containing aromatic molecules generally are much more resistant to radiation degradation than purely aliphatic chain polymers. This is true whether or not the aromatic group is directly in the chain backbone or not. Thus, both polystyrene with a pendant aromatic group and polyimides with an aromatic group directly in the polymer backbone are relatively resistant to high doses (10^9-10^{10}rads) of radiation.[5]

Polymers as used in food packaging often are components of multi-ply laminates. The effects of irradiation on such laminates depend upon the nature of the individual components and the adhesives used to bond the various plies.[6]

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[1]Killoran, " Chemical and Physical Changes in Food Packaging Material," p.377.

[2]Walter M. Urbain, Food Irradiation, (New York: Academic Press, Inc., 1986), p.265.

[3]Skiens, "Sterilizing Effects on Selected Polymer," p.48.

[4]Ibid.

[5]Ibid.

[6]Urbain, Food Irradiation, p.265.

MECHANICAL PROPERTIES OF FLEXIBLE PLASTIC PACKAGING MATERIALS BEFORE AND AFTER IONIZING IRRADIATION

Various studies have been undertaken to measure any changes which might occur in relevant material properties as a consequence of the irradiation process. In this paper, selected reports on the mechanical properties of polymeric material after radiation have been compiled to serve as background information studies. They are intended to help the reader better understand the performance of each irradiated polymer before the results of the actual tests performed on the materials are presented in the following chapter.

The results of the data from this collection of studies are reported in different formats depending upon the objective of each research project. Most of them are in the medical area. The first group of data collected -i.e. the article of David W. Plester, report of H. Landfield, report of J. Cuda and paper from RSI- reports on the radiation stability of polymers used for medical application. These studies constitute a general reference source about the polymers commonly used in the medical field. These reports, however, do not contain specific details about the test method used. Nor is the nature of the end-use character of the polymer, whether it be as film, fiber, or molded polymeric material, indicated.

One of the large earlier research areas was concerned with the changes of the mechanical properties of polymeric materials used for molded devices after irradiation. The research of W.E. Skeins serves as an example. In some of these reports, such as the reports of J. Cuda, parts of the article of David W. Plaster, and the reports of S. DasGupta, the data of the device's packaging testing are included with that of the medical device testing data.

Laminated polymeric materials are dealt with in many food irradiation reports. For Killoran's research carried on at U.S. Army Natick Laboratories, five multilayer materials were tested for the effect of gamma radiation on the mechanical properties. These five films were different types of food contacting film; the outside layer for each laminate was polyethylene terephthalate and the middle layer was aluminum foil. Also, Nielsen has shown that radiation doses up to 30 kGy (3.0 Mrads) have no effect on tensile strength, water vapor transmission rate, and the rate of transmission of oxygen from the polyethylene and polyamide/polyethylene laminate bags.

For the last data group dealing with general polymeric packaging films, information was collected from sources such as George G. Giddings' article, J. F Hanlon's book and Kirsten Nielsen's article.

As W.E Skiens noted in his report "the effects of radiation on thin plastic films and synthetic organic fibre (textiles) may in some cases differ from the effects noticed in bulk products

manufactured from the same or similar polymers. These variations may be due to differences resulting from the processing of these materials. For polymers in these forms which may be in the questionable range for the use of radiation sterilizating techniques, only testing will determine their applicability."[1] I have, thus, summarized the information specifically collected from polymeric packaging films.

POLYAMIDES (NYLONS)

Nylons generally crosslink under the influence of radiation and show a slow increase in tensile strength and hardness, yet a decrease in elongation-at-break with a much more rapid drop in impact strength. Films and fibers are more affected mechanically than thick moldings because the loss of strength arising from the reduction in crystallinity is greater for thin section material than the accompanying increase in strength caused by crosslinking. The presence of oxygen substantially increases the effects of radiation, and such changes will in practice be more important for thin section material.[2] Nylon 6 packaging film can be safely irradiated up to 6 Mrads.[3] When the material received doses of 5.8×10^{16} electron/cm^2, it has the stiffness change of +181%, flexural strength change of +136%, tensile strength change of +107%, and ultimate elongation change of -92%.[4] The nylon 6/6 films showed a severe reduction in tensile strength at 5 Mrads but not at 1.5 and 2.5 Mrads.[5] The nylon 6/6 film can be safely irradiated up to 1 Mrads.[6] When it received radiation of 5.8×10^{16} electron/cm^2, it has the stiffness change of +54%, flexural strength change of +111%, tensile strength change of +80%, and ultimate elongation change of -95%.[7]

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[1]Skiens, "Sterilizing Effects on Selected Polymers," pp.54-55.

[2]D.W. Plester, "The Effects of Radiation Sterilization on Plastics," in Industrial Sterilization, ed. G. Briggs Phillips and W.S. Miller. (Durham, N.C. : Duke University Press, 1973), p. 148.

[3]Nielsen, "Use of Irradiation Technique in Food Packaging," p. 60

[4]Joseph F. Hanlon, Handbook of Package Engineering, (New York: McGraw-Hill Inc.,1984), chapter3 - p.4.

[5]Gidding, "Irradiation of Packaging Materials," p. 79.

[6]Nielsen, "Use of Irradiation Technique," p. 60.

[7]Hanlon, Handbook of Package Engineering, chapter 3 -p.4.

POLYESTERS

Aromatic Polyesters (PET,PETG)

Poly(ethylene terephthalate) is suitable for radiation sterilization whether in film or fiber form. Mechanically it can withstand at least 100 Mrads although discoloration occurs at lower doses. Crosslinking is the major effect of radiation but radiation-induced oxidation can be observed in the presence of air.[1] The laminated PET film is also considered to have a good stability. According to Killoran's report on the effect of gamma ray radiation on the mechanical properties of polyethylene terephthalate multilayered material, there is no great difference noted in tensile, burst and seal strengths of the control and irradiated samples. For this multilayered material, polyethylene terephthalate films are identified as the food contacting film; the outside layer for each laminated film was polyethylene terephthalate and the middle layer was aluminum foil. The adhesive between layers was a cured polyester-epoxy system. The films were irradiated at 6-6.7 Mrad at 21-40°c.[2]

Polyester Film (MYLAR)

MYLAR film is cited as one of the flexible materials that is suitable for at least a single sterilization dose.[3]

POLYOLEFINS

Polyethylene (PE)

Polyethylene film is considered suitable for use as radiation sterilization packaging when the test was conducted with gamma radiation doses of 1.5, 2.5 and 5 Mrads. The film is also listed as a film which can be safely subjected to radiation up to 6 Mrads.[4] PE in general crosslinks with chain scission when irradiated. The average molecular weight increases and the crystallinity decreases.[5] Radiation degradation of polyethylene film is rated 20, this figure is based on micromoles of gas produced from 1 g. of film at 6 Mrads gamma radiation. Different density PE films have different percentage changes of stiffness, flexural strength, tensile strength. However,

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[1]Plester, "The Effects of Radiation Sterilization on Plastics," p.148.

[2]Killoran, "Chemical and Physical Changes in Food Packaging," p.379.

[3]J. Cuda, "Selection of Materials for Radiation Sterilization" Paper presented at the AECL Gamma Radiation Processing Seminar, Ottawa, Ontario, September 29-October 2,1975, p.80.

[4]Gidding, "Irradiation of Packaging Materials," p. 79.

[5]Plester, "The Effects of Radiation Sterilization on Plastics," p.144.

the percentage change of ultimate elongation is approximately the same.[1] The laminated PE film is also considered to have a good stability. According to Killoran's report on the effect of gamma ray radiation on the mechanical properties of high-density polyethylene multilayered material, there is no great difference noted in tensile, burst and seal strengths of the control and irradiated samples. For this multilayered material, high-density polyethylene films are identified as the food contacting film; the outside layer for each laminated film was polyethylene terephthalate and the middle layer was aluminum foil. The adhesive between layers was a cured polyester-epoxy system. The films were irradiated at 6-6.7 Mrad at 21-40°C.[2]

Polypropylene (PP)

The biaxially oriented PP films exhibited a dose-dependent decrease in both tensile strength and elongation-at-break, besides developing the typical yellowish color. Polypropylene film is considered unsuitable for use as radiation sterilization packaging when the test was conducted with gamma radiation doses of 1.5, 2.5 and 5 Mrads.[3] Both chain scission and crosslinking are observed to occur in irradiated PP in about equal amounts. This is due to the fact that PP has a structure intermediate between that of polyethylene, which primarily crosslinks, and polyisobutylene (quaternary carbon atom), which degrades by scission on exposure to radiation. Radiation doses that cause only 25% damage to polyethylene make polypropylene completely useless.[4] Beside chain scission and crosslinking result from irradiating PP, oxidative degradation is an important effect as well. The rate of diffusion of oxygen into the material may be controlled by dose rate. Items irradiated at high dose rates, such as can be achieved by electron beams, may therefore show much less damage than those treated at the low dose rates of other irradiation methods.[5] Crosslinking is evidently the major factor at low doses because the impact strength suffers an immediate fall followed by a slow decay over a period of months. Even after 2.5 Mrad, the impact strength can decrease eventually by more than 50%. Discoloration also occurs in polypropylene, which often turns a noticeable yellow after a single dose of sterilization, although this can be alleviated by using a blue tinted material.[6] Although significant damage may occur at doses of 2 Mrad or less, stabilization is available to help prevent embrittlement on newer materials.

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[1]Hanlon, Handbook of Package Engineering, chapter 3 - p.4.

[2]Killoran, "Chemical and Physical Changes in Food Packaging Materials," p.379.

[3]Gidding, "Irradiation of Packaging Materials," p.79.

[4]Skiens, "Sterilizing Effects on Selected Polymer," p.51.

[5]Plester, "The Effects of Radiation Sterilization on Plastics," p.145.

[6]Ibid.

Effects may increase with time even one month after irradiation.[1] Radiation degradation of common polypropylene film is rated at 20, this figure is based on micromoles of gas produced from 1g. of film at 6 Mrads gamma ray radiation.[2]

POLYSTYRENE

Polystyrene (PS)

Polystyrene film has the most radiation stability. For common PS polymer, doses of more than 100 Mrads may not cause significant damage and multiple sterilization is possible. However, there is a slightly yellow discoloration.[3] The aromatic rings in the structure appear to provide protection against radiation effects.[4] Radiation degradation of common polystyrene film is rated at <1 (unaffected), this figure is based on micromoles of gas produced from 1 g. of film at 6 Mrads gamma radiation. When receiving radiation of 5.8×10^{16} electron/cm^2, Polystyrene general-purpose film has the stiffness change of -13%, flexural strength change of -24%, tensile strength change of -50%, and ultimate elongation change of -45%. At the same radiation dose, polystyrene-butadiene, high impact film has the stiffness change of +99%, flexural strength change of +51%, tensile strength change of -35%, and ultimate elongation change of -92%.[5] The high impact polystyrene film coated with saran is also considered suitable for use as the radiation sterilization packaging material when the test was conducted with gamma radiation doses of 1.5, 2.5 and 5 Mrads.[6]

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1 Radiation Sterilizers Incorporated, "Radiation Sterilization - Materials Considerations" RSI Gammagram, (Illinois: Radiation Sterilizers Incorporated, 1988), p.1.

[2]Hanlon, Handbook of Package Engineering, chapter 3 - p.4.

[3]Radiation Sterilizers Incorporated, "Radiation Sterilization," p.1.

[4]Plester, "The Effects of Radiation Sterilization on Plastics," p.146.

[5]Hanlon, Handbook of Package Engineering, chapter 3 - p.4.

[6]Gidding, "Irradiation of Packaging Materials," p.79.

Chapter III
HYPOTHESES

In this research project, the major interest is to study the mechanical properties of plastic film before and after irradiation. Two aspects of the study will be concentrated in this report and selected mechanical tests will be performed as part of the study. Hypotheses are drew for these two aspects using statistical analysis.

The first study concentrates on whether or not there are any changes in mechanical properties of plastic packaging film after irradiation.

In one material, the change in mechanical strength properties after irradiation can be indicated by the difference between the means of the mechanical properties before and after irradiation. In order to observe the differences among more than two sample means, the statistical tool used for this purpose is the analysis of variance. This statistical test requires that the hypothesis is stated in a "null" form, where tests are conducted to determine whether or not the difference between the sample means is significant.[1] Therefore, the hypothesis for this study is:

1. At the 0.05 level of significance, the mechanical strengths of non-irradiated material and of irradiated material treated with dose levels of 2.5, 5.0, 7.5, and 10 Mrad are equal. (There is no significant difference between sample means at 0.05 level of significance.)

The null hypothesis would be supported if the differences between sample means are small (less than or equal to 5%) and would be rejected if at least some of the differences between the sample means are large (more than 5%).

The second study concentrates on the relationship between dose level and its effects on the mechanical properties of the material.

The relationship between radiation dose levels and their effects on mechanical properties will be expressed by the coefficient of correlation (r) and the coefficient of determination ($100\ r^2$).

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[1]John E. Freund, Modern Elementary Statistics, (New Jersey : Prentice-Hall, 1988) p.383

The coefficient of correlation (r) must lie on the interval from -1 to +1. If r =0, none of the variations of the mechanical properties can be attributed to their relationship with radiation doses of 2.5 Mrad. and above.[1] However, due to the collected studies supported that all polymer are effected by ionizing radiation, this r value is expected to be useful in catagorizing the relationship between the variation of mechanical properties and the radiation doses of 0.0, 2.5, 5.0, 7.0 and 10.0 Mrads instead of being used to imply the cause-effect relationship between the two variables.

The coefficient of determination (100 r^2) is the percentage of the total variation of the mechanical properties due to different radiation dose treatments. This, in itself, is an important measure of the relationship between two variables. Beyond this, it permits valid comparisons of the strength of several relationships.[2] Using this statistical tool called "the correlation", the following hypothesis must be tested :

2. As the radiation doses are ranked at 2.5 Mrad and above, different materials would have different strengths in their linear relationship between dose levels and their effect on mechanical properties. The polypropylene (PP) and the oriented-polypropylene (OPP) are expected to have the strongest relationship.

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[1]Freund, Modern Elementary Statistics, p.457

[2]Ibid., p.459

Chapter IV
METHODOLOGY

The process used to conduct this research project is listed as follows:

1. Prepare for the experiment.
2. Perform the experiment by following the procedures.
3. Perform data analysis on the data resulting from the experiment in order to study any changes in the mechanical properties and the relationship between radiation doses and effects.

PREPARATION FOR THE EXPERIMENT

SELECTION OF THE MECHANICAL PROPERTY TESTING METHOD

The standard test method for Tensile Properties of Thin Plastic Sheeting (Reference: ASTM D 882-83) was selected for the mechanical property testing method of this research.

The tensile test is one of the most important tests used to measure the strength of materials and it was found to be the most used testing method in the reports collected for this research. During the tensile tests, a sample of material is elongated in uniaxial tension at a constant rate and the load necessary to produce the given elongation is measured as a dependent variable. The tensile testing of common plastic films is unique, they have relatively high elongation and can exhibit a yield strength which is relatively higher than breaking strength while a material like paper has very minor elongation prior to break and exhibits a relatively straight stress-strain curve.[1]

The tensile test yields much data on properties such as strain, toughness and stiffness of material. In this experiment, two mechanical properties of plastic film samples will be calculated from the testing data by using the following formula:

1. Average tensile strength = $\frac{\text{average load at break}}{\text{(sample width x thickness)}}$

2. Average percent elongation at break = $\frac{\text{average elongation at break}}{\text{grip separation}} \times 100$

[when average elongation at break = $\frac{\text{average chart movement}}{\text{(chart speed / crosshead speed)}}$]

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[1]Daniel L. Goodwin, A. Ray Chapman, and Deanna M. Jacobs, Method of Evaluation-Laboratory Manual, (New York: R.I.T., Department of Packaging Science,1984), p.72

SELECTION OF PLASTIC FILM SAMPLES

Eight polymeric films which are commonly used in the food and medical industries were selected for the samples in this experiment. They are as fellows:

1. Polyethylene Terephthalate (PETG): This is a PET (Polyethylene Terephthalate) film which is modified to permit certain types of melt processing. It is a tough, clear transparent material, rather similar to PET in some important food-related properties. This film exhibits good resistance to oils, organic solvents and chemicals.[1] (PETG is a FDA approved polymeric film: CFR 179.45 for food which irradiated with a maximum dose of 6 Mrads.[2])

2. Polyester/Polyethylene Film: This is a commonly used material for food flexible food containers. It has also been generally found to be satisfactory for use with radurized haddock fillets.[3]

3. Polypropylene Film (PP): Unoriented polypropylene film was introduced in the late 1950's. Polypropylene is a crystalline polymer with a melting point of about 170°C.[4] Unmodified cast film offers good yield, clarity, and grease and moisture resistance.[5]

4. Oriented-Polypropylene film (OPP): Drawing or stretching cast PP significantly changes or enhances its properties. Specifically orienting or stretching improves impact resistance and increases tensile strength and the work function. Low temperature properties are enhanced, and optical properties, moisture barrier, and grease and fat resistance are all increased.[6]

5. Polyethylene Film (PE): Properties that make polyethylene film a popular packaging medium are its low price, toughness, flexibility over a wide temperature range, pleasing appearance and softness, chemical inertness, relatively high oxygen and carbon dioxide permeabilities, and low water-vapor permeability.[7] (PE film is a FDA approved polymeric film: CFR 179.45 for food which irradiatied with a maximum dose of 6 Mrads.[8])

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[1]Calvin J. Benning, Plastic Films for Packaging, (Pennsylvania: Technomic Publishing, 1983), p.55.

[2]See Appendix D: FDA Approved Polymeric Films: CFR 179.45.

[3]Urbain, Food Irradiation, p.267.

[4]Benning, Plastic Films, p.112.

[5]Ibid., p.37.

[6]Ibid.

[7]Ibid., p.114

[8]See Appendix D: FDA Approved Polymeric Films: CFR 179.45.

6. Polyester Film (MYLAR): The only oriented form of common polyester film which has applications. This film is tough, sterilizable, clear, chemical resistant and has low WVTR. It is an ideal base for packaging laminates.[1]

7. Polyester/Nylon Film: The applications of this laminated film can be found in various packagings such as those used for vacuum packs, processed meat and cheese, boil-in-pouch, bake-in-bag, and hospital-medical purposes.[2]

8.Polystyrene Film(PS): This film's properties are clarity, crisp feel, and low moisture barrier. It has been often used for bagging lettuce.[3] (PS film is a FDA approved polymeric film: CFR 179.45 for irradiated food packaging which allowed a maximum exposure dose of 1 Mrads.[4])

PREPARATION OF FILMS SAMPLES FOR IRRADIATION
AT SELECTED RADIATION DOSES

According to reports on testing polymeric materials for medical use, the radiation doses usually used are 1.5, 2.5, and 5.0 Mrads.[5] In addition, the majority of commercial gamma radiation facilities currently process sterilization jobs with the maximum dose of 10.0 Mrads. Therefore, the doses of 2.5, 5.0, 7.0, and 10.0 Mrads were selected to be the radiation doses for the plastic film samples in this experiment.

The selected plastic film samples were prepared for irradiation as follows:

1. Films with the width of approximately 1.5 ft. were cut into four pieces which measured 20 yards each. Films with shorter widths could be cut into four pieces which measured more than 20 yards.

2. For each material, four pieces of film were rolled into four rolls. Each roll has a diameter of about 1.0-1.5 inches (except MYLAR film which has a the diameter of about 3.0-4.0 inches due to its stiffness). The films were rolled tightly and fastened with masking tape.

3. Each of the four 8"x8"x25" C-flute corrugated boxes was marked to indicate each one of the four different doses: 2.5, 5.0, 7.0 and 10.0 Mrads. Each box was irradiated with the dose as marked. One roll of each material was placed into each box so that each box would contain eight films.

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[1]Benning, Plastic Films, p.56.

[2]Ibid., p. 116.

[3]Ibid., p.115.

[4]See Appendix D: FDA Approved Polymeric Films: CFR 179.45.

[5]Gidding,"Irradiation of Packaging Materials," p.78 and Landfield, "Effects of Radiation," p.41.

4. Four boxes was consolidated into one box (size 16 7/8" x16 7/8" x 25 1/2" C-flute corrugated box) for shipping. The United Parcel Service (UPS) delivered this box both ways, to the gamma radiation facility in Illinois and back to Rochester Institute of Technology in New York.

THE EXPERIMENT PROCEDURE

TEST METHOD Tensile Properties of Thin Plastic Sheeting

MATERIALS Eight selected films, both non-irradiated film and film irradiated with doses of 2.5, 5.0, 7.0 and 10.0 Mrads.

REFERENCE ASTM D 882-83

EQUIPMENT
1. Instron Tensile Tester
2. JDC Sample Cutter, Model JDC-25
3. The Dead Weight Vertical Micrometer
4. Record Sheet.

PROCEDURE
1. Check the film thickness by the dead weight vertical micrometer. Measure at least two spots on each film to determine the average thickness of the sample.
2. For each material, cut 40 samples to size 1"x7" with the sample cutter :
   - 20 samples (at least) for machine direction (MD)
   -20 samples (at least) for transverse direction (TD)

This number of samples will yield 20 sets of tensile data for each direction for one film.

3. At the Instron Tensile Tester machine, set up the following parameters and try pulling a couple of samples in order to have the break occur at approximately mid-range of the chart (If graph is too tall, increase load range-kg; do the opposite if graph is too small). Also, chart movement (mm) should occur in the appropriate length.

Grip separation - 50 mm (2"), 75 mm (3") or 100 mm (4").
Crosshead speed -12.5, 50, or 500 mm/min.
Chart speed - 20, 50, or 100 mm/min.

(These are the suggested numbers; they may be different for some films.)

4. Perform actual test to acquire 40 sets of data by using one set of the most appropriate parameters found from step #3, above.

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[1]See Appendix F: Data Sheet.

5. Read the chart. Record 40 sets of data of load at break (kg) and 40 sets of data of chart movement (mm). Include sample width, sample thickness and the three parameters discussed in step #3, above, in the record sheet. All this information is necessary for the calculation of tensile strength and elongation at break.

6. Do the parameter set up (see step #3, above) when starting to work with the next film. A suitable set of parameters must be found for each type of film.

DATA ANALYSIS

DATA ANALYSIS OBJECTIVE

The purpose of my data analysis is to find the following three statistical values for each film direction (MD and TD) of eight different film sample:

1. F-ratio, from the statistical method, "Analysis of Variance."
2. The coefficient of correlation (r), from the statistical method, "Correlation."
3. The coefficient of determination ($100r^2$), also from the "Correlation" method.

1. F-Ratio, from the Statistical Method "Analysis of Variance"

"Analysis of Variance" is the statistical tool used to observe the difference between more than two sample means.[1] In one material, F-ratio will help support the first hypothesis that there is no difference between the mechanical properties of samples irradiated with five different doses: 0.0, 2.5, 5.0, 7.0 and 10.0 Mrads. at the 0.05 level of significance. (Tensile strength and elongation at break(%) represent the mechanical properties of the samples.)

The comparison of the changes in one mechanical property is only made within a group consisting of each of the five samples of the same film subjected to a different dose of radiation. The null hypothesis would be supported if the differences between the five sample means are small, and the null hypothesis would be rejected if at least some of the differences between the sample means are large.[2] To establish the comparison on a rigorous basis, we use the F statistic or a variance ratio:

$$F = \frac{\text{mean square (MS) factor}}{\text{mean square (MS) error}} = \frac{\text{the variation of mechanical properties among 5 different dose groups}}{\text{the variation due to random error}}$$

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[1] Freund, Modern Elementary Statistics, p.380.

[2] Ibid., p.381.

F is very large when the MS factor is much larger than the MS error, that is when the variation of mechanical properties among five different dose groups is much greater than the variation due to random error.[1] In such cases, we will reject the null hypothesis which states that the film has no change in mechanical properties after irradiation with doses of 2.5, 5.0, 7.0, and 10.0 Mrads.

How large the F-ratio must be in order to reject the null hypothesis is determined by an F-table. To use this table, we need the degrees of freedom for the numerator of the F-ratio and the degrees of freedom for the denominator of the F-ratio.[2] These two parameters would come from the parameters used in the testing method of this research,

-the numerator has 4 degrees of freedom [(k-1)= (5-1)= 4, when k= five different dose group.]
-the denominator has 95 degrees of freedom [k(n-1)= 5(20-1)= 5(19) = 95,
when n= 20= sample size of each dose group.][3]

So, the corresponding value from an F-table using $F_{0.05}$ (0.05 level of significance) is about 2.53.[4]

Therefore, the null hypothesis will be rejected if F is larger than 2.53.

2. The coefficient of correlation (r) from the statistical method "Correlation"

There are several ways to measure the association between two variables. The most common measure is the Pearson product moment correlation coefficient, or "correlation" for short. This is usually designated by the letter r.[5] Due to the collected studies supported that all polymer are effected by ionizing radiation, this r value will help me to catagorize the relationship between the variation of mechanical properties and the irradiation doses of 0.0, 2.5, 5.0, 7.0 and 10.0 Mrads instead of being used to imply the cause-effect relationship between the two variables.

The correlation coefficient is always between -1 and +1.[6] In this research, the two variables are irradiation doses (Mrads) and mechanical property. The r can predict the association between two variables only when it is accompanied by a graph plotted between the two variables.

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[1]Barbara F. Ryan, Brian L. Joiner, and Thomas A. Ryan.Jr., Minitab Handbook -2nd.ed., (Boston: PWS-KENT Publishing,1985), p.197.

[2]Ibid.

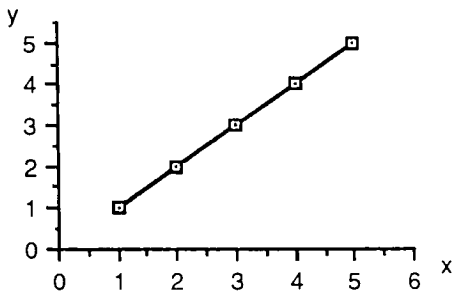
[3]Freund, Modern Elementary Statistics, p.383

[4]See Appendix G: Table 4. Value of $F_{0.05}$ for the F Distribution.

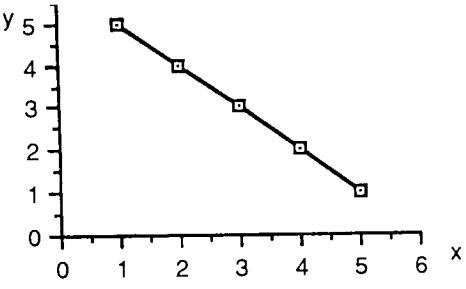
[5]Ryan, Joiner, and Ryan.Jr., Minitab Handbook , p.218.

[6]Ibid.

If there is association between radiation doses and mechanical property, the plot tends to be linear and the (r) can be explained as follows:



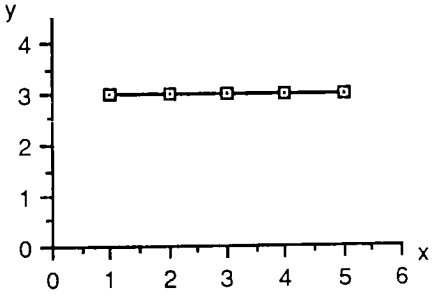
1. If r is positive ($+r$), the mechanical property tends to increase as the radiation dose increases. A plot between two variables will show the slopes upward. If the points fall exactly on a straight line, then r = +1.The closer r is to +1, the closer the points will be to forming a straight upwardly slanted line.



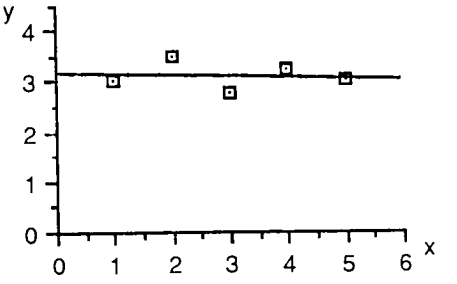
2. If r is negative ($-r$), the mechanical property tends to decrease as the radiation dose increases. A plot between the two variables will show the slopes downward. If the points fall exactly on a straight line, then r = -1.The closer r is to -1, the closer the point will be to forming a straight downwardly slanted line.

If there is no association between radiation doses and the mechanical property, then r can be explained as follows:

1. the r = 0 or r will be near 0 while a plot is linear.

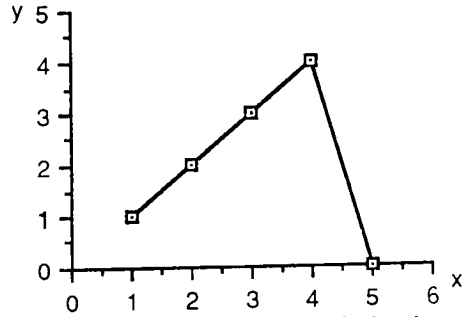


a. the r is 0 while a plot is linear.

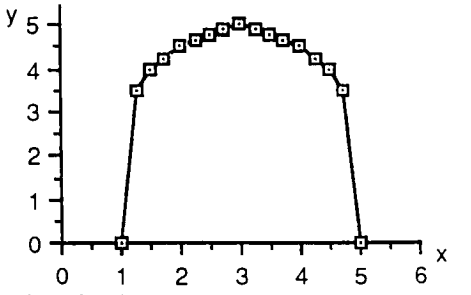


b. the r will be near 0 while a plot is linear.

2. the r is close to +1 or -1 while a plot is not linear as follows:



a. the point x=5 makes the whole plot mean that that there is no correlation between the two variables.



b. the plot lies on a curve instead of on a linear line.

3. The Coefficient of Determination (100 r^2), also from the "Correlation" method.

This value will help measure the relationship between the mechanical properties and the five different radiation doses. Also, this will allow me to compare how strong the relationship between the mechanical property and radiation doses of 0.0, 2.5, 5.0, 7.0, and 10.0 Mrads in each of the eight different films. In this research project, the polypropylene and the oriented polypropylene are expected to have the strongest relationship.

In general, the definition of r tells us that $100r^2$ is the percentage of the total variation of the mechanical property which is due to its relationship with the radiation doses of 0.0, 2.5, 5.0, 7.0, and 10.0 Mrads.[1] The $100r^2$ is needed for the comparison between the strengths of the relationships because r alone can be misleading. For instance, one might calculate that r = -0.80 in one study and r = 0.40 in another study. The correlation 0.40 seems to indicate a stronger relationship than the correlation -0.80. However, when r = -0.80, then $100(-0.80)^2$ = 64 percent of the variation of the mechanical property which is due to their relationship with the five radiation doses, while when r = 0.40, then $100(0.40)^2$ = 16 percent of the variation of the mechanical property which is due to their relationship with the five radiation doses. Thus, in the sense of "percentage of variation accounted for," it can be said that the -0.80 correlation is four times as strong as the 0.40 correlation.

The correlation (r) needs to be identified before using the coefficient of determination (100 r^2). The film which showed no correlation between irradiation doses and mechanical property will be excluded from the relationship strength comparison of the eight different films.

DATA ANALYSIS ON MINITAB®

TOOL

1. VAX/VMS computer system at Rochester Institute of Technology (R.I.T).
2. MINITAB® statistical computer software, available in VAX A, VAX B, VAX C and VAX D of VAX/VMS computer system at R.I.T.

PROCEDURE

The MINITAB® command file is written down in order to program the software to perform the following calculations:[2]

1. Convert the data unit from kilogram (kg) to pound (lb) and from millimeter (mm) to inch (in) by setting the MINITAB® arithmetic command and using the conversion factors as follows:

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[1]Freund, Modern Elementary Statistics, p.459.

[2]See Appendix H: Minitab Command Files Constructed for this Data Analysis.

- the data of load at break : kg ÷ 0.454 = lb.
- the data of chart movement, grip separation, sample width and sample thickness: mm ÷ 25.4 = inch.
- the data of chart speed and crosshead speed: mm per min ÷ 25.4 = inch per min.

2. Calculate two mechanical properties: tensile strength (psi- pound per square inch) and elongation at break (%). The arithmetic commands are set up according to the following formula:

$$\text{Tensile strength (psi)} = \frac{\text{load at break (lb)}}{\text{sample width (in) x thickness (in)}}$$

$$\text{Percent elongation at break (\%)} = \frac{\text{elongation at break (in)}}{\text{grip separation (mm)}} \times 100$$

$$\text{[when elongation at break (in)} = \frac{\text{chart movement (in)}}{\text{chart speed(in/min)/ crosshead speed(in/min)}}\text{]}$$

3. Use the following statistical command -ONEWAY analysis of variance- to find the F-ratio of tensile strength and F-ratio of elongation of the film:
"ONEWAY AOV ON DATA IN C2, SUBSCRIPTS IN C1"[1]
(C1 = radiation doses, C2 = tensile strength or elongation at break values)
The value will help me to analyze whether there are any changes on both properties when the film is irradiated with different doses.
4. Use the following statistical command to find the coefficient of correlation (r):
"CORRELATION C1-C3"[2]
(C1 = radiation doses, C2 = tensile strength values, C3 = %elongation values)
5. Calculate the coefficient of determination (100 r^2). The arithmetic command is set up according to the following formula:
the coefficient of determination ($100r^2$) = 100 x [coefficient of correlation(r)^2].

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[1]Minitab Inc., Minitab Statistical Software Reference Manual - Release 6.1, (Boston: PWS-KENT Publishing,1985) p.140.

[2]Ibid., p.101.

Chapter V
RESULTS

RESULTS OF THE STATISTICAL ANALYSIS UNDERTAKEN IN THE FIRST STUDY:
WHETHER OR NOT THERE IS ANY DIFFERENCE BETWEEN MECHANICAL PROPERTIES IN THE FILMS IRRADIATED WITH DOSES OF 0.0, 2.5, 5.0, 7.0, AND 10.0 MRADS.

1.Tensile Strength

Table 1. Result of the F-ratio calculated from the variation of tensile strength in five samples of one type of film each exposed to a different radiation dose (0.0, 2.5, 5.0, 7.0 and 10.0 Mrads).

film	film direction*	F -ratio (tensile)	F ≤ 2.53	F ≥ 2.53
1.PETG	MD	6.06		√
	TD	21.51		√
2. Polyester/PE	MD	51.24		√
	TD	55.15		√
3. PP	MD	96.87		√
	TD	110.65		√
4. OPP	MD	301.56		√
	TD	244.75		√
5. PE	MD	34.55		√
	TD	2.46	√	
6. Polyester (MYLAR)	MD	34.04		√
	TD	100.02		√
7. PE/Nylon	MD	6.63		√
	TD	10.82		√
8. PS	MD	7.16		√
	TD	48.63		√

* MD = machine direction, TD = transverse direction

As explained in the section entitled "Data Analysis" (Chapter IV,p.36), the differences in tensile strength of a film irradiated with different doses is not significant if

$$F = \frac{\text{MS Factor}}{\text{MS Error}} \leq 2.53$$

As shown in table 1, since the F-ratio of every eight film except PE(TD) is greater than 2.53, it can be concluded that the variation in tensile strength of five samples of one type of film each exposed to a different radiation dose is significant (at 0.05 level of significant). Therefore, the null hypothesis is rejected.

Only PE(TD) film has the F-ratio less than 2.53. It can be concluded that the variation in tensile strength for the five samples of PE(TD) film is not significant (at 0.05 level of significance). Therefore, the null hypothesis is accepted only for the tensile strength of PE(TD) films.

2. Percentage elongation at break (%)

Table 2. Result of the F-ratio calculated from the variation of % elongation at break in five samples of one type of film each exposed to a different radiation dose (0.0, 2.5, 5.0, 7.0 and 10.0 Mrads).

film	film direction*	F -ratio(%elongation)	F ≤ 2.53	F ≥ 2.53
1.PETG	MD	7.87		√
	TD	6.92		√
2. Polyester/PE	MD	1.62	√	
	TD	7.85		√
3. PP	MD	5.63		√
	TD	16.75		√
4. OPP	MD	185.62		√
	TD	138.67		√
5. PE	MD	5.25		√
	TD	1.66	√	
6. Polyester (MYLAR)	MD	20.35		√
	TD	7.16		√
7. PE/Nylon	MD	216.45		√
	TD	338.55		√
8. PS	MD	3.48		√
	TD	5.75		√

* MD = machine direction, TD = transverse direction

As explained in the section entitled "Data Analysis" (Chapter IV, p.36), the differences in percentage elongation at break of a film irradiated with different doses is not significant if:

$$F = \frac{\text{MS Factor}}{\text{MS Error}} \leq 2.53$$

As shown in table 2, since the F-ratio of all the sample films except PE(TD) and polyester/PE(MD) is greater than 2.53, it can be concluded that the difference in percentage elongation at break for those types of films irradiated with the different doses is significant (at 0.05 level of significance). Therefore, the null hypothesis is rejected.

Only PE(TD) film and polyester/PE(MD) film have F-ratios that are less than 2.53. It can be concluded that the different variation in percentage elongation at break of PE(TD) and polyester/PE(MD) film subjected to the five different doses is not significant (at 0.05 level of significance). Therefore, the null hypothesis is accepted for percentage elongation at break of both PE(TD) film and polyester/PE(MD) film.

SUMMARY FOR THE FIRST STUDY

1. According to the statistical analysis, at the 0.05 level of significance, the films PETG(MD&TD), Polyester/PE(TD), PP (MD&TD), OPP (MD&TD), PE(MD), Polyester-MYLAR (MD&TD), PE/Nylon (MD&TD), and PS (MD&TD) exhibit significant changes in mechanical properties (both tensile strength and percentage elongation at break) when irradiated with doses of 0.0, 2.5, 5.0, 7.0 and 10.0 Mrads.

2. At the 0.05 level of significance, PE(TD) film exhibits no significant change in mechanical properties (either tensile strength or percentage elongation at break) when irradiated with doses of 0.0, 2.5, 5.0, 7.0 and 10.0 Mrads.

2. At the 0.05 level of significance, Polyester/PE(MD) film exhibits no significant change in percentage elongation at break when irradiated with doses of 0.0, 2.5, 5.0, 7.0 and 10.0 Mrads.

RESULTS OF STATISTICAL ANALYSIS IN THE SECOND STUDY:

THE RELATIONSHIP BETWEEN THE MECHANICAL PROPERTIES OF IRRADIATED FILMS AND RADIATION DOSES OF 0.0, 2.5, 5.0, 7.0, AND 10.0 MRADS.

The degree of relationship between mechanical properties and radiation doses of less than 10.0 Mrads [0.0 (non-irradiated), 2.5, 5.0, 7.0, and10.0 Mrads] found in this study can be catagorized into three types: the dose-dependent, the dose-independent, and the weak correlation. The statistical analysis "correlation" is used to help identify the relationship type for each film as follows:

As explained in the section entitled, "Data Analysis" (Chapter IV, p. 36), the relationship between the mechanical properties of one film and radiation doses will be identified by a graph plotted with these two variables and by using the *r* value (coefficient of correlation).

By using this statistical tool, a correlation between the mechanical properties and radiation doses for a given type of film can be deduced if the mechanical strength decreases significantly (r close to-1) or increases significantly (r close to +1) and continues to decrease or increase as the radiation dose increases from 0.0 Mrads to 10.0 Mrads. This type of film will be called "dose-dependent".

On the other hand, films for which the data shows no correlation between the mechanical properties and radiation doses will generally yield two types of results from which these films can then be categorized into two groups. For the first group of films, the mechanical strength has a very low r or an r close to 0 and the plot is linear. The results show a weak relationship because there is a very small change in the mechanical strength of the film caused by radiation doses from 2.5 Mrads to 10.0 Mrads. This type of film will be called "weak correlation" The mechanical properties of this type of film is considered radiation resistant at doses up to 10.0 Mrads. For the second group, the mechanical strength of the film has either a very high r (r close to +1 or -1) or a very low r (r close to 0) and the plot is not linear. The mechanical strength plot (x-plot) shows a decrease ($-r$) or an increase ($+r$) but does not decrease or increase constantly as the irradiation doses increases from 0.0 Mrads to 10.0 Mrads. The graph will show the highest or the lowest mechanical strength value at some specific dose between 0.0 Mrads to 10.0 Mrads but not at either of these two doses. This type of film will be called "dose-independent". In this report, the specific dose will be identified at which the films in this group exhibited their highest or lowest mechanical strength.

Any type of films for which a correlation between the two variables exists will be compared to the other samples of this group of films by using the $100r^2$ (coefficient of determination). This value measures the strength of the relationship between the mechanical properties and radiation doses. The result responds to the second hypothesis whether or not the polypropylene (PP) and the oriented-polypropylene (OPP) have the strongest relationship. The films which exhibit the strongest relationship tend to be most easily affected by radiation in the dose range of 2.5 Mrads to 10.0 Mrads.

In the following pages the data will be analyzed in order to determine the relationship between the mechanical properties and radiation doses of each film by using the r value (coefficient of correlation). The analysis will be accompanied by graphs plotted with the values of the two variables. Then, all results will be summarized at the end of this chapter.

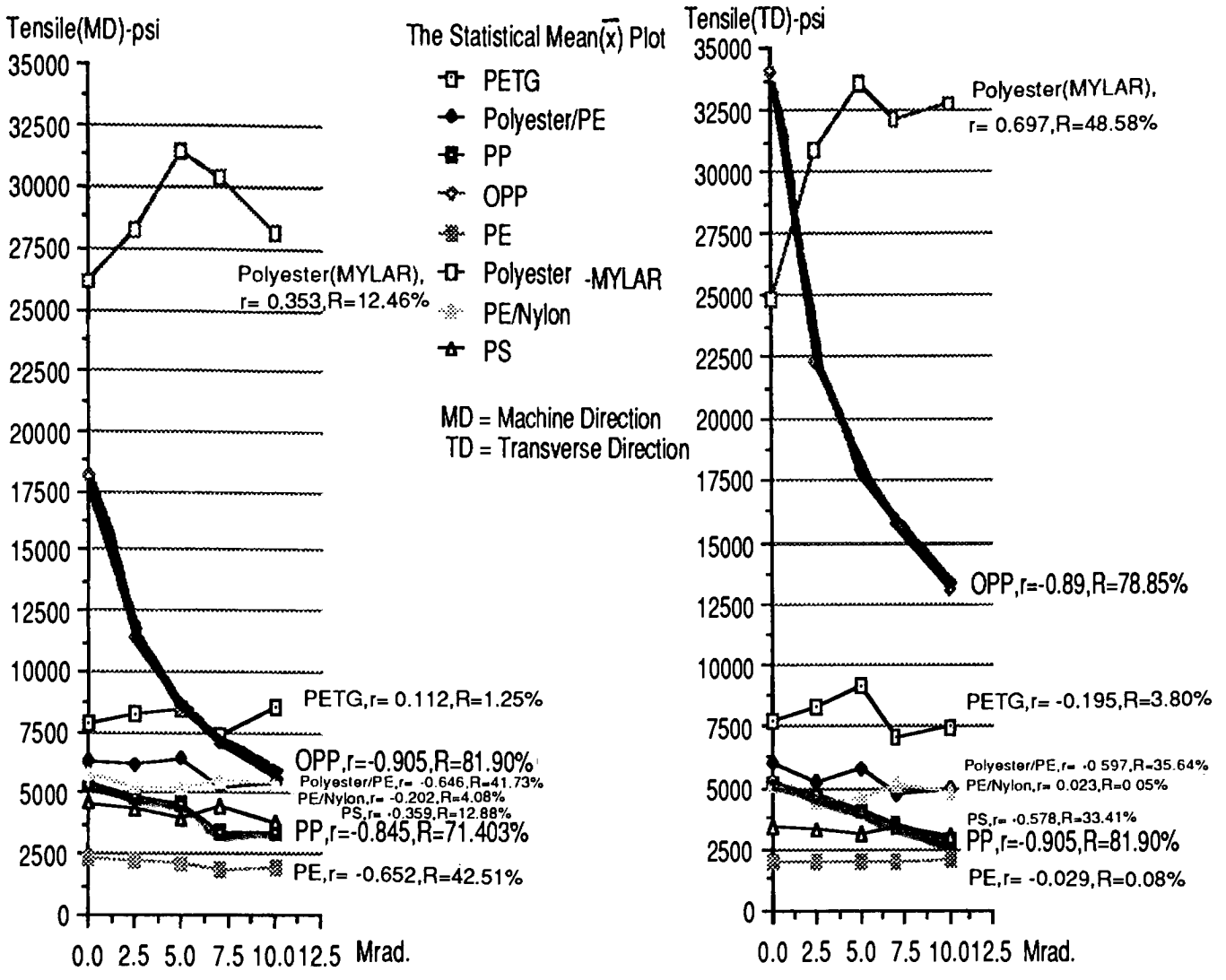


Figure 1. The correlation between radiation doses or "Mrads" and tensile strength or "psi"

By considering the r value as well as the graph, the correlation is identified as follows:

PP(MD&TD) and OPP(MD&TD) films show a correlation between tensile strength and irradiation doses in the range of 0.0 Mrads to 10.0 Mrads. These films are called "dose-dependent". Because the graph shows tensile strength to decrease consistently as the radiation dose increases from 0.0 Mrads to 10.0 Mrads. Also, the r is high (close to -1), points on the graph nearly form a straight line.

OPP(MD) and PP(TD) have the strongest correlation due to the highest coefficient of determination [$(100r^2)$ or R = 81.90% for OPP(MD) and R = 81.90% for PP(TD)].

The rest of film samples were determined to show no correlation between the two variables. They are either "dose-independent" or "weak correlation". Further information is presented in table 3.

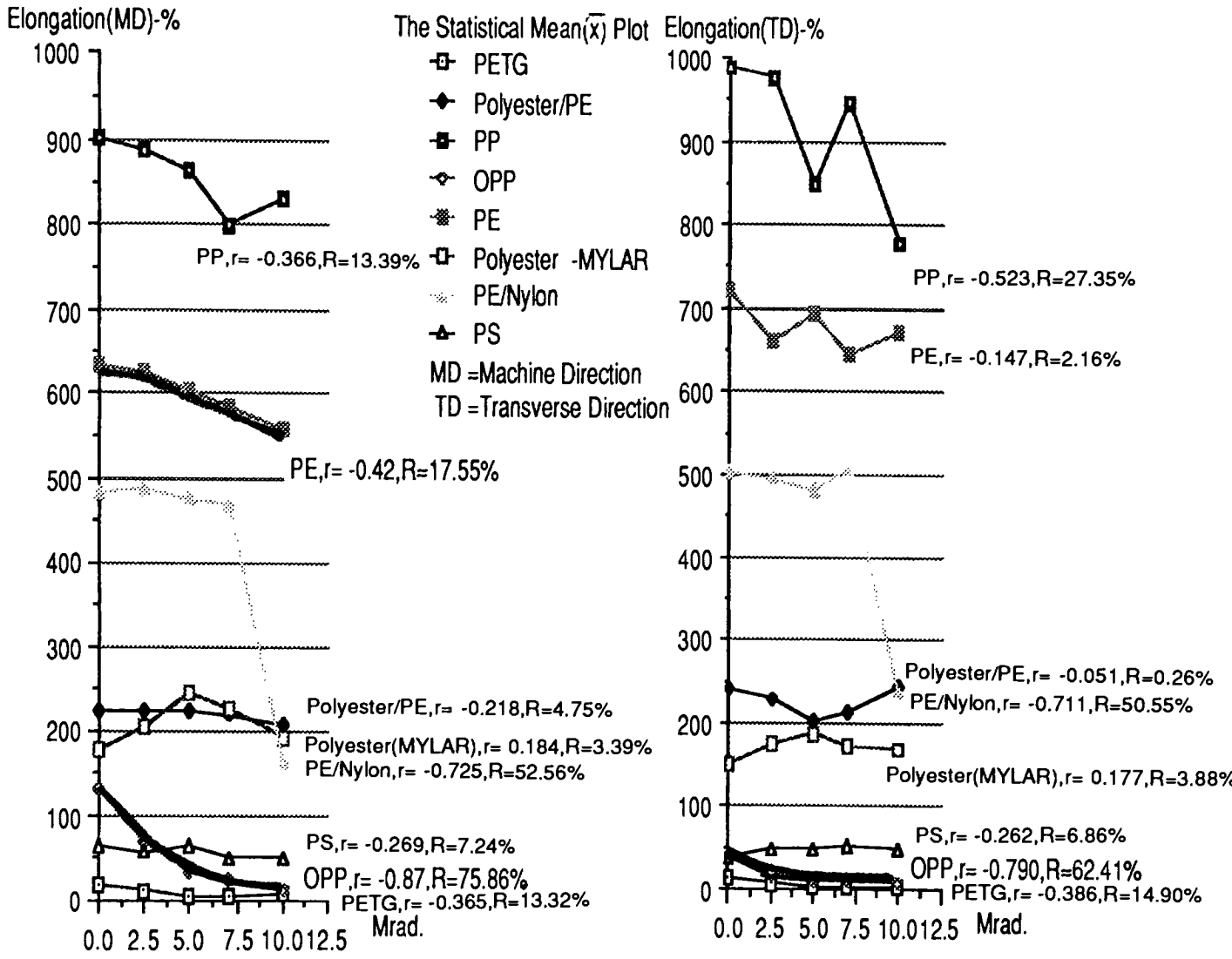


Figure 2. The correlation between radiation doses or "Mrads" and percentage elongation at break or "%"

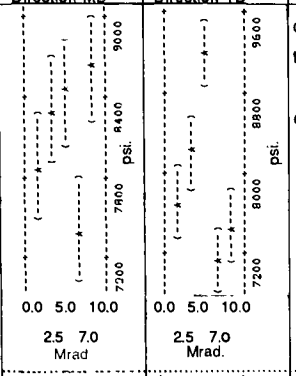
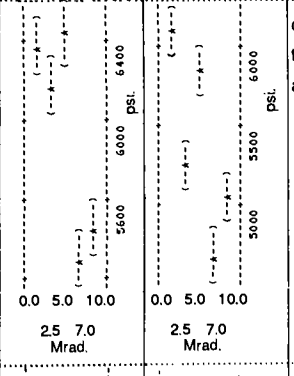
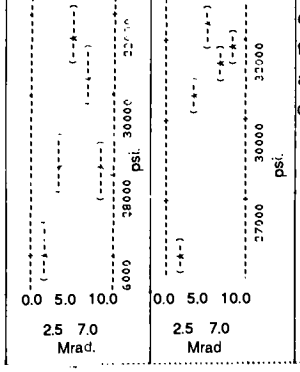
By considering the *r* value as well as the graph, the correlation is identified as follows:

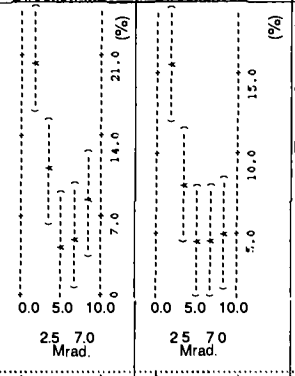
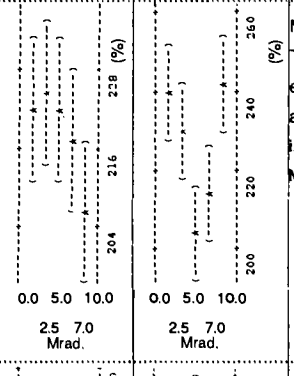
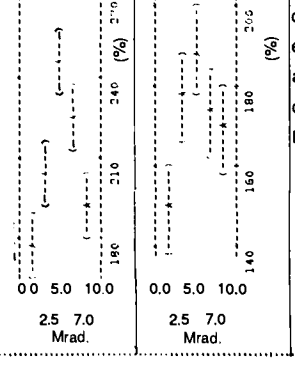
OPP(MD&TD) and PE(MD) films show a correlation between percentage elongation at break and radiation doses in the range of 0.0 Mrads to 10.0 Mrads. These films are called "dose-dependent". Because the graph shows percentage elongation at break to decrease consistently as the radiation dose increases from 0.0 Mrads to 10.0 Mrads. Also, the *r* is high (close to -1), points on the graph nearly form a straight line.

OPP(MD&TD) have the strongest correlation due to the highest coefficient of determination [$(100r^2)$ or R = 75.86% for OPP(MD) and R = 62.41% for OPP(TD)].

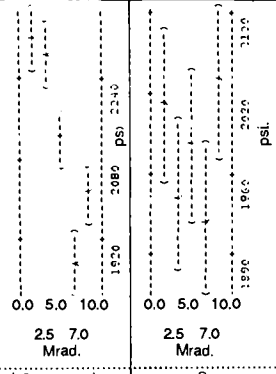
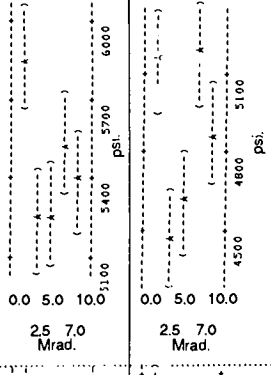
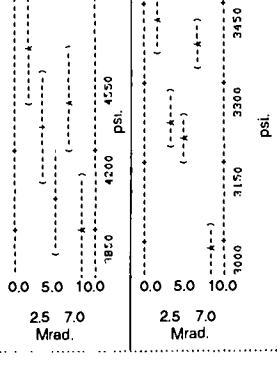
The rest of film samples were determined to show no correlation between the two variables. They are either "dose-independent" or "weak correlation". Further information is presented in table 3.

Table 3. SUMMARY OF THE RESULTS

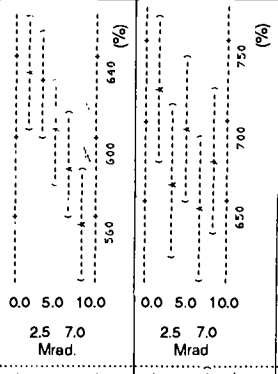
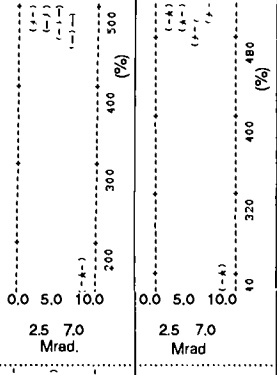
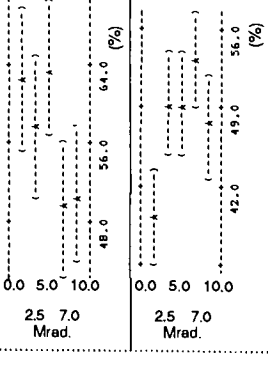
Film	TENSILE STRENGTH (PSI)						Remarks on relationship between tensile strength and radiation doses 0.0 2.5, 5.0, 7.0 and 10.0 Mrads.
	At 0.05 level of significance, the tensile strength changes after irradiation		The correlation exists between tensile strength and radiation doses.		* Individual 95% CI'S for mean base on pooled standard deviation		
	Yes	No	Yes	No	Machine Direction-MD	Transvarse Direction-TD	
PETG	√			√			dose-independent tensile strengths increase at 5.0 Mrads then decrease at 7.0 Mrads.
Polyester/ PE	√			√			dose-Independent tensile strengths decreases at 7.0 Mrads.
Polyester (MYLAR)	√			√			dose-Independent tensile strengths Increase at 5.0 Mrads then decrease at 7.0 Mrads.

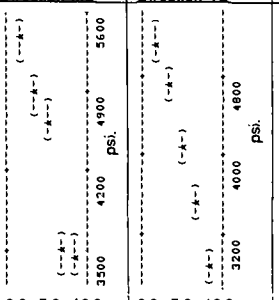
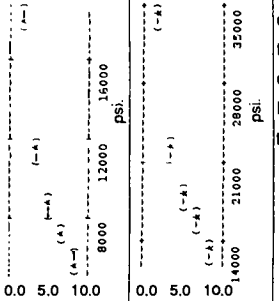
Film	PERCENTAGE ELONGATION AT BREAK (%)						Remarks on relationship between elongation(%) and radiation doses 0.0 2.5, 5.0, 7.0 and 10.0 Mrads.
	At 0.05 level of significance, the elongation(%) changes after irradiation		The correlation exists between elongation(%) and radiation doses.		* Individual 95% CI'S for mean base on pooled standard deviation		
	Yes	No	Yes	No	Machine Direction-MD	Transverse Direction-TD	
PETG	√			√			dose-Independent elongation(%) decrease at 5.0 Mrads then Increase at 7.0 and 10.0 Mrads.
Polyester/ PE	√ TD	√ MD		√			MD - weak correlation. TD - dose-Independent elongation(%) decreases at 5.0 Mrads then Increase at 7.0 and 10.0 Mrads.
Polyester (MYLAR)	√			√			dose-Independent elongation(%) Increase at 5.0 Mrads then decrease at 7.0 and 10.0 Mrads.

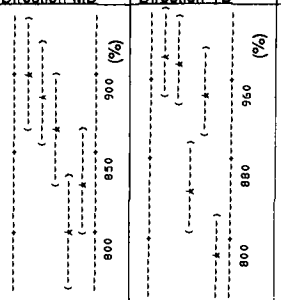
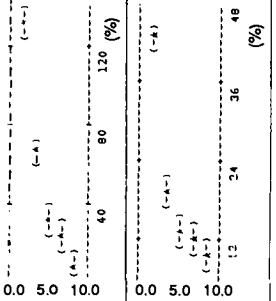
TENSILE STRENGTH (PSI)

Film	At 0.05 level of significance, the tensile strength changes after irradiation		The correlation exists between tensile strength and radiation doses.		*Individual 95% CI'S for mean base on pooled standard deviation		Remarks on relationship between tensile strength and radiation doses 0.0, 2.5, 5.0, 7.0 and 10.0 Mrads.
	Yes	No	Yes	No	Machine Direction-MD	Transverse Direction-TD	
PE	√ MD	√ TD		√			dose-Independent MD- tensile strength decrease at 7.0 Mrads then Increase at 10.0 Mrads. TD- weak correlation.
PE/ Nylon	√			√			dose-Independent tensile strengths decreases at 5.0 Mrads then Increase at 7.0 Mrads.
PS	√			√			dose-Independent tensile strengths decrease at 5.0 Mrads then Increase at 7.0 Mrads.

PERCENTAGE ELONGATION AT BREAK (%)

Film	At 0.05 level of significance, the elongation(%) changes after Irradiation		The correlation exists between elongation(%) and radiation doses.		*Individual 95% CI'S for mean base on pooled standard deviation		Remarks on relationship between elongation(%) and radiation doses 0.0, 2.5, 5.0, 7.0 and 10.0 Mrads.
	Yes	No	Yes	No	Machine Direction-MD	Transverse Direction-TD	
PE	√ MD	√ TD	√ MD	√ TD			MD- dose-dependent elongation(%) decreases as doses increase from 0.0 to10.0 Mrads. TD- weak correlation.
PE/ Nylon	√			√			dose-Independent elongation(%) decreases at 10.0 Mrads.
PS	√			√			dose-Independent MD- elongation(%) decrease at 7.0 Mrads. TD-elongation(%) Increases at 7.0 Mrads.

Film	TENSILE STRENGTH (PSI)						
	At 0.05 level of significance, the tensile strength changes after irradiation.		The correlation exists between tensile strength and radiation doses.		* Individual 95% CI'S for mean base on pooled standard deviation		Remarks on relationship between tensile strength and radiation doses 0.0, 2.5, 5.0, 7.0 and 10.0 Mrads.
	Yes	No	Yes	No	Machine Direction-MD	Transverse Direction-TD	
PP	√		√				dose-dependent tensile strengths decrease as doses increase from 0.0 Mrad to 10.0 Mrads.
OPP	√		√				dose-dependent tensile strengths decrease as doses increase from 0.0 Mrad to 10.0 Mrads.

Film	PERCENTAGE ELONGATION AT BREAK (%)						
	At 0.05 level of significance, the elongation(%) changes after irradiation.		The correlation exists between elongation(%) and radiation doses.		* Individual 95% CI'S for mean base on pooled standard deviation		Remarks on relationship between elongation(%) and radiation doses 0.0, 2.5, 5.0, 7.0 and 10.0 Mrads.
	Yes	No	Yes	No	Machine Direction-MD	Transverse Direction-TD	
PP	√			√			dose-Independent MD- elongation(%) decreases at 7.0 Mrads. TD- elongation(%) decreases at10.0 Mrads.
OPP	√		√				dose-dependent elongation(%) decrease as doses increase from 0.0 Mrad to 10.0 Mrads.

* From MINITAB® Analysis of Variance. See example in Appendix I, p. 75

Chapter VI
CONCLUSIONS AND RECOMMENDATIONS

In this study, two mechanical properties, tensile strength and percentage elongation at break, of eight plastic films have been found to change after irradiation with doses of less than 10.0 Mrads (2.5, 5.0, 7.0, and 10.0 Mrads). However, in order to establish rigor in this analysis so as to identify satisfactorily radiation-resistant films, the statistical level of significance of 0.05 was set. This means that the variation in a mechanical property of a film irradiated with the five different doses used, 0.0 (non-irradiated), 2.5, 5.0, 7.0, and10.0 Mrads, must be less than 5% in order for it to be concluded that there is no change in the mechanical property of the film after irradiation. By setting the 0.05 level of significance, only polyethylene film (transverse direction-TD) is found to undergo no significant change in either tensile strength or percentage elongation at break. The polyester/polyethylene film (machine direction-MD) is found to change only in percentage elongation at break. The rest of the film samples -PP(MD&TD), OPP(MD&TD), polyester/PE(TD), polyester-MYLAR(MD&TD), PE(MD), PE/Nylon(MD&TD) and PS(MD&TD)- are found to exhibit a variation in mechanical properties after irradiation of more than 5%, when compared with the other samples of the same film type.

The degree of correlation between mechanical properties and radiation doses of less than 10.0 Mrads [0.0 (non-irradiated), 2.5, 5.0, 7.0, and10.0 Mrads] found in this study can be catagorized into three types: the dose-dependent, the dose-independent, and the weak correlation.

Only oriented polypropylene film (OPP) is found to have a dose-dependent relationship between radiation dose and both tensile strength and percentage elongation at break; both mechanical properties decreased as the dose increased. Polypropylene film (PP) is found to have the same correlation, but only with one mechanical property, tensile strength. According to these results, OPP film will weaken in tensile strength and become more brittle as the radiation dose increases from 0.0 to 10.0 Mrads. PP film will weaken in tensile strength as the dose increase but may not become so brittle after the 5.0 Mrads, since the percentage elongation at break does not continue to decrease from doses 7.0 to 10.0 Mrads.

Polyethylene film (MD) is found to have the same correlation but only with one mechanical property, percentage elongation at break. Thus, PE (MD) film will become more brittle as the dose increases from 0.0 to 10.0 Mrads, due to a corresponding decrease in percentage elongation at break.

The rest of the film samples are found to have no obvious correlation as described above. For example, polyester-MYLAR film shows an obvious dose-independent relationship in that both mechanical properties significantly increase from 0.0 to 5.0 Mrads and then drop at 7.0 Mrads. The two films discussed in the first analysis, polyethylene film (TD) and polyester/polyethylene(MD), of which the mechanical properties changed less than 5% after irradiation, obviously showed a weak correlation between radiation dose and both mechanical properties. However, categorizing the rest of the film samples as either dose-independent or as exhibiting a weak correlation must take into account further considerations for these film can fall into a different category depending upon the level of significance used.

Films shown to have no correlation between mechanical properties and radiation dose level can be classified as either dose-independent or weak correlation types. Examples of such films are PETG film and polyester/PE film which exhibit a tensile strength increase from 0.0 to 5.0 Mrads, a drop at 7.0 Mrads and then an increase again at 10.0 Mrads. Because the statistical level of significance had been set at 5% for the first analytical study, these films are considered dose-independent. In other words, for each film type, the change from highest tensile strength at 5.0 Mrads to lowest at 7,0 Mrads is greater than 5% and therefore regarded as significant. However if, in practice, the highest and the lowest tensile strength resulting from a film irradiated at 5.0 and 7.0 Mrads causes no more damage to the end-use packaging than non-irradiated film, then variation in tensile strength would not be considered significant. The correlation would be classified as a weak correlation type.

In the second analysis, films such as PS and PE(MD) are found to exhibit a weak correlation; there exists literature which supports their radiation resistant properties. However, the mechanical properties of these films after irradiation changed more than 5%; thus the change is significant using the criteria of the first analysis. Therefore, the relationship is considered dose-independent type.

From these results, it is concluded that the mechanical properties of films exhibit certain changes after irradiation and that these changes have different correlations with radiation doses of less than 10.0 Mrads. In this paper, the purpose is not to determine whether a film is suitable or not for irradiation since other factors, such as those described above, must be considered and these are beyond the scope of this study. The purpose is to present the data and analysis of the effect of different dose levels on each individual film in a format that will most benefit packaging personnel.

It is recommended that all concerns, such as choice of radiation source and type of sterilization, be considered when utilizing irradiated packaging film.[1] For example, the packaging plan for gamma radiation is required to have the limit of a minimum and maximum dose which is not in too narrow a range since gamma radiation does not issue from a machine controlled source as does electron radiation. For packaging which is specified to be irradiated at 6.0 Mrads, one must set the limits of a minimum dose of 6.0 ± 0.1 and a maximum dose of 6.7 Mrads. Therefore, the selected packaging film has to be able to withstand a dose in that range and within the exposure time of gamma radiation. A packaging film which allows for, for instance, a 1.5 Mrads minimum dose and which has no maximum dose limit for radiation pre-sterilization of the empty film package may be the most preferred material for gamma radiation sterilization.

Further recommended areas of study on the mechanical properties of plastic films after irradiation would be the study of the effect of certain temperatures, light levels, oxygen levels and storage times on the mechanical properties of irradiated films. Although the literature supports that variation in these variables causes changes in the mechanical properties of irradiated film, consideration of these factors have been chosen to not include in this research project. One phenomena found during this experimentation has interesting implications. The outer layer of the roll of irradiated material samples generally exhibited more damage than the inner layer of film within the same roll. The effect is noticeable but has not yet been measured for evaluation. These plastic film samples are rolled very tightly when prepared for gamma radiation. One area for further study could be whether the density of the packaging arrangement for gamma radiation shows any correlation with the changes in the mechanical properties of films after irradiation.

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[1]See Chapter II, under sections entitled "The Ionizing Treatment Facility" and "How Packaging Material Are Irradiated During the Commercial Food Irradiation Process".

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Appendix A:

Comparison of Sterilization Methods.

Comparison of Sterilization Methods.

Consideration	Steam	Ethylene Oxide	Gamma Radiation
1. Product Design	No Sealed Cavity	No Sealed Cavity	No Restrictions
2. Materials of Construction	Most Materials Satisfactory except for those which are Heat or Moisture Sensitive	Most Materials Satisfactory	Most Materials Satisfactory
3. Product Packaging	Permeable Material or Second Sealing Process	Permeable Material or Second Sealing Process	No Restrictions
	Provision for Expansion of Packaging during Vacuum	Provision for Expansion of Packaging during Vacuum	No Restrictions
	Seals must withstand Vacuum Stress	Seals must withstand Vacuum Stress	No Restrictions
4. Parameters to be Controlled during Sterilization	Vacuum Pressure Temperature Relative Humidity Time	ETO Concentration Vacuum Pressure Temperature Relative Humidity Time	Time
5. Reliability of Sterilizing Process	Good	Good	Excellent
6. Post Sterilization Microbioloigical Testing	Desirable	Required	Can be Eliminated
7. Quarantine Period	7 – 14 Days	7 – 14 Days	Can be Eliminated
8. Post Sterilization Treatment	Dry Product	Aerate to Remove Toxic Residues	None
9. Quantitative Process Monitoring Possible	No	No	Yes
10. Economics	Good on Low and High Volumes	Good on Low and High Volumes	Good On High Volumes

Source : George G. Giddings, Information Bulletin - Isomedix Inc, (New Jersey: Isomedix Inc., 1984)

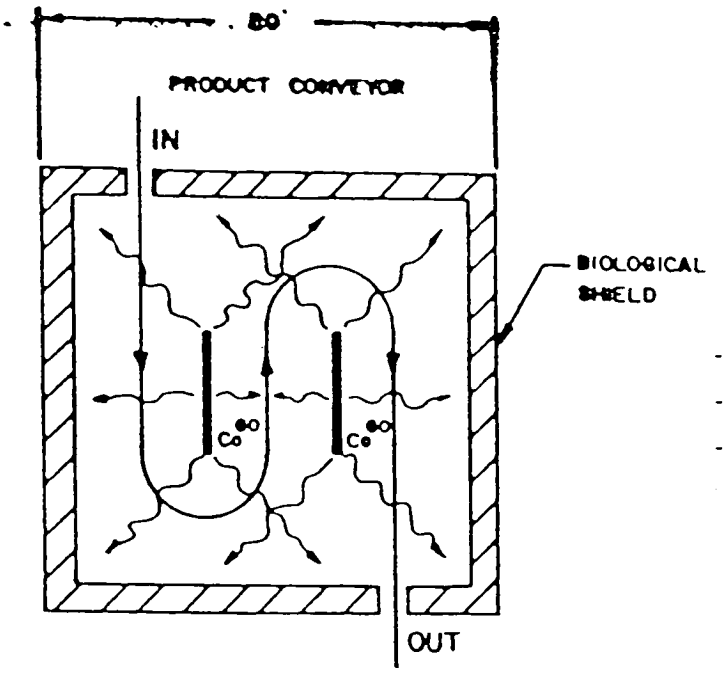
Appendix B:

Figure 3. Typical Radiation Sterilizers - Gamma Radiation and Electron Beam Radiation.

Figure 4. Commercial Gamma Radiation Facility
- Radiation Sterilizers Inc. (RSI), U.S.A.

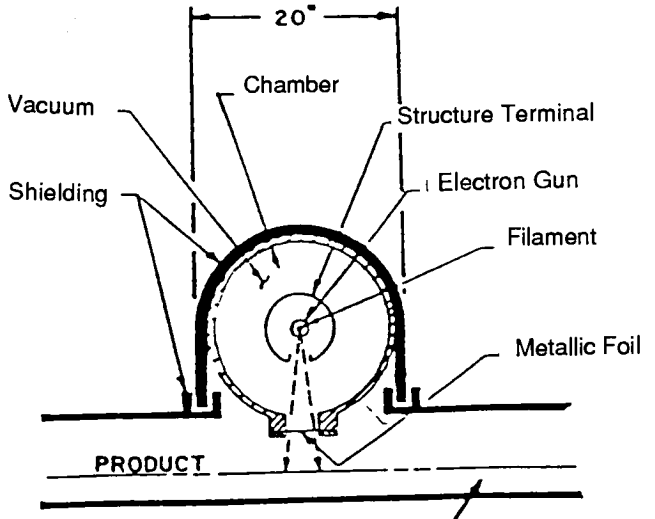
Figure 5. Commercial Electron Beam Radiation Facility
- CGR MeV, a division of General Electric, France.

Figure 3. Typical Radiation Sterilizers - Gamma Radiation and Electron Beam Radiation.



(a) GAMMA (BULK)

- less cost : use small amt. rad.
- slow process
- use for bulk irradiation

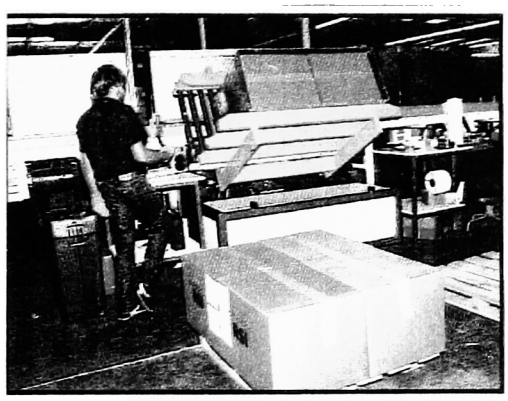


(b) ELECTRON (SURFACE) — ASEPTIC TUNNEL

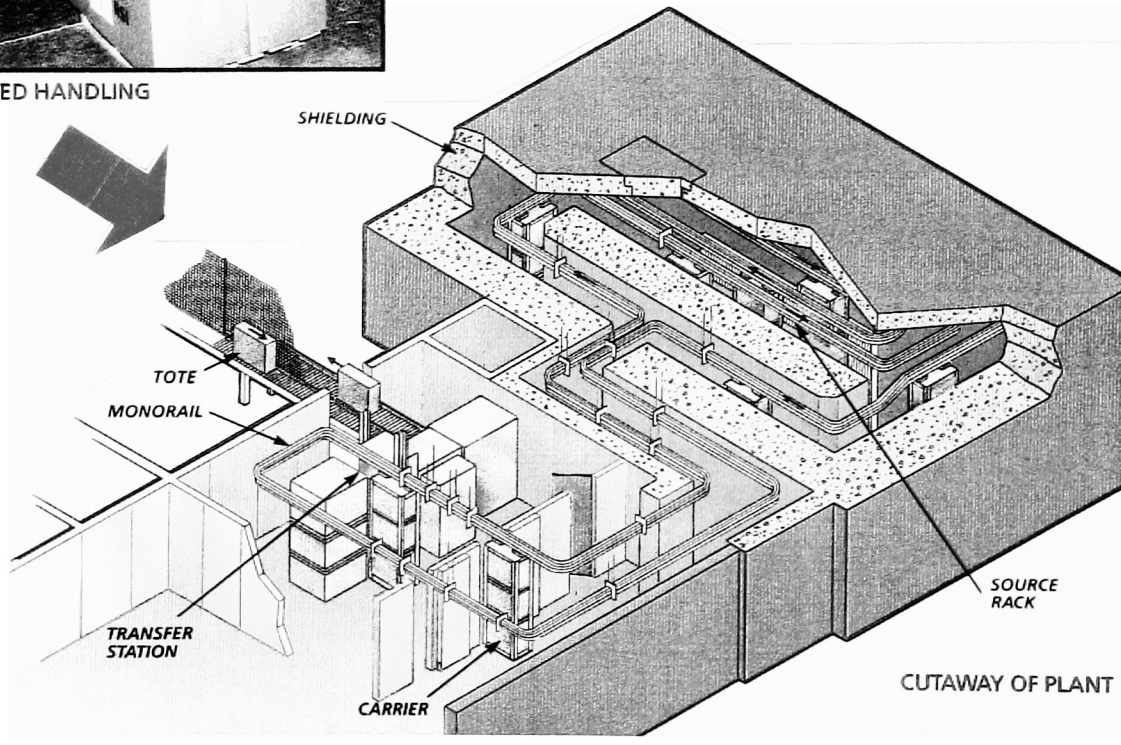
- costly
- fast process
- surface irradiation
- use for in-line irradiation

source : Judith N. Aaronson and Sam V. Nablo. " Electron Bean Sterilization Its monitoring and control. " Paper presented at the Symposium on Applications and Advances in Aseptic technology, Aseptic Processing and Packaging, North Carolina State University, Raleigh, NC, November 10-14, 1986. p.12.

Figure 4. Commercial Gamma Radiation Facility
- Radiation Sterilizers Inc. (RSI), U.S.A.



AUTOMATED HANDLING

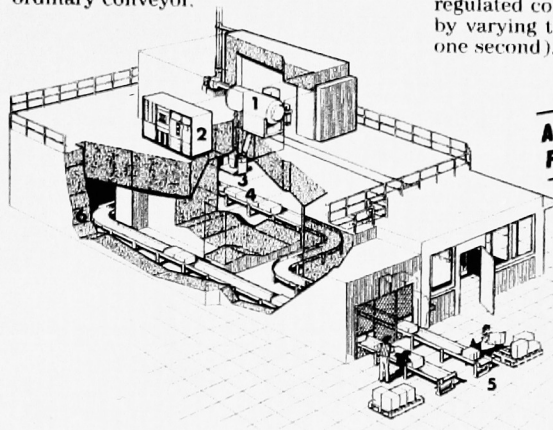


Source : GA Technologies Inc. "Gamma Wave™." Commercial brochure by TRIGA Reactor Division, GA Technologies Inc., California, 1985.

Figure 5. Commercial Electron Beam Radiation Facility
- CGR MeV, a division of General Electric, France.

The products are transported from the storage area to the ionization room by an ordinary conveyor.

The electrons produced by the accelerator penetrate the products which move on a regulated conveyor. The dose is obtained by varying the exposure time (less than one second).



AN INDUSTRIAL TOOL FOR THE IONIZING TREATMENT

1. Accelerator
2. Modulator
3. Scanning horn
4. Regulated conveyor
5. Loading/unloading post
6. Concrete wall for biological shielding

PRODUCTS	PURPOSE	ELECTRON MODE THROUGHPUT T/h*	X MODE THROUGHPUT T/h*
Onions Potatoes Garlic	Inhibition of sprouting	–	65
Grains	Desinfestation	45	–
Fruits	Desinfestation	–	6.5
Poultry Meat Sea food	Bacteriological decontamination	12	–
Spices Medicinal plants	Bacteriological decontamination	6	–
Medical disposable supplies	Sterilization	From 18 to 48 m³/h	–

*Tons per hour

Penetration depends on the density (δ) of the products and the energy (E) of the electrons.
Industrial penetration (double-side treatment allowing the treatment of thicker products and improving the dose homogeneity):

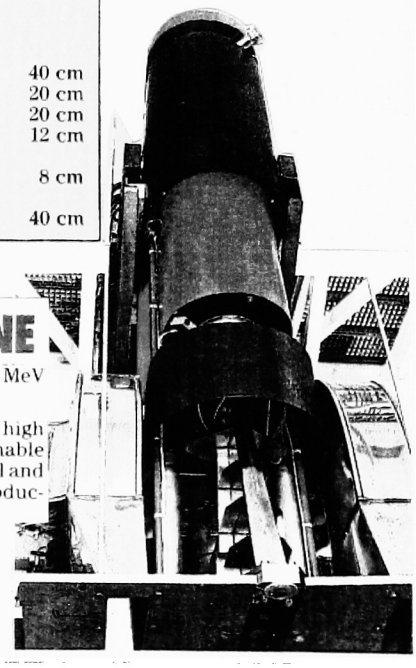
$$\frac{0.8\ E\ (MeV)}{\delta\ (g/cm^3)} = \ldots\ cm$$

ex. of penetration for 10 MeV energy electrons

- medicinal herbs ($\delta = 0.2$) 40 cm
- spices ($\delta = 0.4$) 20 cm
- mushroom boxes ($\delta = 0.4$) 20 cm
- poultry ($\delta = 0.6$) 12 cm
- mechanically separated poultry meat ($\delta = 1$) 8 cm
- medical disposable supplies ($\delta = 0.2$) 40 cm

CIRCE II LINE

The power of this machine ranges from 10 to 30 kW for 10 MeV energy.



CASSITRON LINE

is a 5 to 10 kW power and 8 to 10 MeV energy accelerator.

The CASSITRON, producing high dose rates and having reasonable dimensions, is an industrial tool and can be easily inserted in a production line system.

Source : CGR MeV. "An Industrial Tool for A New Technology Ionization." Commercial brochure by CGR MeV - a division of General Electric in Buc, France, 1987.

Appendix C:

List of Clearances (As of March 22,1988.)

List of Clearances (As of March 22,1988.)

				kGy	
UNITED STATES OF AMERICA	wheat and wheat	insect disinfestation	unconditional	0,2-0.5	21 August 1963
	white potatoes	shelf-life extension	unconditional	0.05 - 0.1	30 June 1964
	white potatoes	shelf-life extension	unconditional	o.05 - 0.15	1 November 1965
	spices and dry vegetable seasoning (38 commodities)	decontamination/ insect disinfestation	unconditional	30 (max.)	5 July 1983
	dry or dehydrated enzyme preparations (including immobilized enzyme preparations)	control of insects and/or micro-organisms	unconditional	10kGy (max.)	10 June 1985
	pork carcasses or fresh, non-heat processed cuts of pork carcasses	control of Trichinella spiralis	unconditional unconditional	0.3 (min) - 1.0 (max.)	22 July 1985
	fresh foods	delay or maturation	unconditional	1	18 April 1986
	food	disinfestation	unconditional	1	18 April 1986
	dry or dehydrated enzyme preparations	decontamination	unconditional	10	18 April 1986
	dry or dehydrated aromatic vegetable substances	decontamination	unconditional	30	18 April 1986

Source : Joint FAO/IAEA Division of Isotope and Radiation Applications of Atomic Energy for Food and Agricultural Development, Supplement to Food Irradiation Newsletter Vol.12, No.1, April 1988, (Vienna: International Atomic Energy Agency (IAEA), 1988), p. 15.

Appendix D:

FDA Approved Polymeric Films: CFR 179.45.

FDA Approved Polymeric Films: CFR 179.45.

Material	Description of approved material	Maximum radiation dose, kGy
Nitrocellulose or vinylidene chloride coated cellophane	177.1200	10*
Wax coated paperboard	176.170	10*
Glassine paper	176.170	10*
Polyolefin	175.1520	10*
Kraft paper	176.170	5*
Polystyrene	176.1630	10*
Rubber hydrochloride	175.300	10*
Nylon hydrochloride	177.1500	10*
Polyethylene	177.1530	60*
Polyethylene terephthalate	177.1630	60*
Polyiminocyproyl (nylon 6)	177.1500	60*
Vinylidene chloride-vinyl chloride	175.320	60*
Vinyl chloride-vinyl acetate	175.320	60*
Vegetable parchment	179.45	60*
Ethylene-vinyl acetate	177.1350	80*

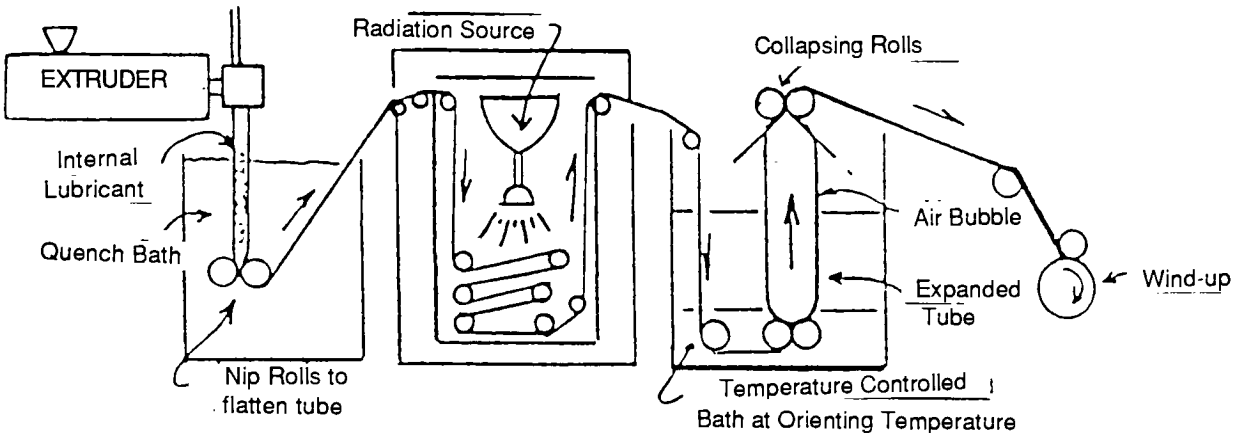
Incidental to use of gamma radiation.
Incidental to use of gamma or electron radiation.

Source: Code of Federal Regulations, (Washington, D.C.: Office of the Federal Register National Archives and Records Administration), April 1,1988.

Appendix E:

Figure 6. Process for Biaxially Orienting Film of Irradiated Polyethylene.

Figure 6. Process for Biaxially Orienting Film of Irradiated Polyethylene.



Source : Calvin J. Benning, Plastic Films for Packaging, (Pennsylvania: Technomic Publishing Co., 1983), p. 67

Appendix F:

Data Sheet

Data Sheet

	____mm	____inches
Sample Length	____mm	____inches
Sample Thickness	____mm	____inches
Grip Seperation	____mm	____inches
Chart Speed	____mm/min.	
Cross Head Speed	____mm/min.	
Load Range	____kg	

SAMPLE	LOAD AT BREAK kg	CHART MOVEMENT mm	LOAD AT YIELD kg	CHART MOVEMENT mm	LOAD AT TANGENT kg	CHART MOVEMENT mm
# 1 MD			—			
2 MD						
3 MD						
4 MD						
5 MD						
6 MD						
7 MD						
8 MD						
9 MD						
10 MD						
11 MD						
12 MD						
13 MD						
13 MD						
14 MD						
15 MD						
16 MD						
17 MD						
18 MD						
19 MD						
20 MD						
# 1 CD						
2 CD						
3 CD						
4 CD						
5 CD						
6 CD						
7 CD						
8 CD						
9 CD						
10 CD						
11 CD						
12 CD						
13 CD						
14 CD						
15 CD						
16 CD						
17 CD						
18 CD						
19 CD						
20 CD						
AVE. LOAD AT BREAK	MD		AVE. LOAD AT YIELD	MD	AVE. LOAD AT TANGENT	MD
	CD			CD		CD

Appendix G:

Table 4. Value of $F_{0.05}$ for the F Distribution.

Table 4. Value of $F_{0.05}$ for the F Distribution.

Degrees of freedom for denominator	Degrees of freedom for numerator														
	1	2	3	4	5	6	7	8	9	10	12	15	20	24	30
1	161	200	216	225	230	234	237	239	241	242	244	246	248	249	250
2	18.5	19.0	19.2	19.2	19.3	19.3	19.4	19.4	19.4	19.4	19.4	19.4	19.4	19.5	19.5
3	10.1	9.55	9.28	9.12	9.01	8.94	8.89	8.85	8.81	8.79	8.74	8.70	8.66	8.64	8.62
4	7.71	6.94	6.59	6.39	6.26	6.16	6.09	6.04	6.00	5.96	5.91	5.86	5.80	5.77	5.75
5	6.61	5.79	5.41	5.19	5.05	4.95	4.88	4.82	4.77	4.74	4.68	4.62	4.56	4.53	4.50
6	5.99	5.14	4.76	4.53	4.39	4.28	4.21	4.15	4.10	4.06	4.00	3.94	3.87	3.84	3.81
7	5.59	4.74	4.35	4.12	3.97	3.87	3.79	3.73	3.68	3.64	3.57	3.51	3.44	3.41	3.38
8	5.32	4.46	4.07	3.84	3.69	3.58	3.50	3.44	3.39	3.35	3.28	3.22	3.15	3.12	3.08
9	5.12	4.26	3.86	3.63	3.48	3.37	3.29	3.23	3.18	3.14	3.07	3.01	2.94	2.90	2.86
10	4.96	4.10	3.71	3.48	3.33	3.22	3.14	3.07	3.02	2.98	2.91	2.85	2.77	2.74	2.70
11	4.84	3.98	3.59	3.36	3.20	3.09	3.01	2.95	2.90	2.85	2.79	2.72	2.65	2.61	2.57
12	4.75	3.89	3.49	3.26	3.11	3.00	2.91	2.85	2.80	2.75	2.69	2.62	2.54	2.51	2.47
13	4.67	3.81	3.41	3.18	3.03	2.92	2.83	2.77	2.71	2.67	2.60	2.53	2.46	2.42	2.38
14	4.60	3.74	3.34	3.11	2.96	2.85	2.76	2.70	2.65	2.60	2.53	2.46	2.39	2.35	2.31
15	4.54	3.68	3.29	3.06	2.90	2.79	2.71	2.64	2.59	2.54	2.48	2.40	2.33	2.29	2.25
16	4.49	3.63	3.24	3.01	2.85	2.74	2.66	2.59	2.54	2.49	2.42	2.35	2.28	2.24	2.19
17	4.45	3.59	3.20	2.96	2.81	2.70	2.61	2.55	2.49	2.45	2.38	2.31	2.23	2.29	2.15
18	4.41	3.55	3.16	2.93	2.77	2.66	2.58	2.51	2.46	2.41	2.34	2.27	2.19	2.15	2.11
19	4.38	3.52	3.13	2.90	2.74	2.63	2.54	2.48	2.42	2.38	2.31	2.23	2.16	2.11	2.07
20	4.35	3.49	3.10	2.87	2.71	2.60	2.51	2.45	2.39	2.35	2.28	2.20	2.12	2.08	2.04
21	4.32	3.47	3.07	2.84	2.68	2.57	2.49	2.42	2.37	2.32	2.25	2.18	2.10	2.05	2.01
22	4.30	3.44	3.05	2.82	2.66	2.55	2.46	2.40	2.34	2.30	2.23	2.15	2.07	2.03	1.98
23	4.28	3.42	3.03	2.80	2.64	2.53	2.44	2.37	2.32	2.27	2.20	2.13	2.05	2.01	1.96
24	4.26	3.40	3.01	2.78	2.62	2.51	2.42	2.36	2.30	2.25	2.18	2.11	2.03	1.98	1.94
25	4.24	3.39	2.99	2.76	2.60	2.49	2.40	2.34	2.28	2.24	2.16	2.09	2.01	1.96	1.92
30	4.17	3.32	2.92	2.69	2.53	2.42	2.33	2.27	2.21	2.16	2.09	2.01	1.93	1.89	1.84
40	4.08	3.23	2.84	2.61	2.45	2.34	2.25	2.18	2.12	2.08	2.00	1.92	1.84	1.79	1.74
60	4.00	3.15	2.76	2.53	2.37	2.25	2.17	2.10	2.04	1.99	1.92	1.84	1.75	1.70	1.65
120	3.92	3.07	2.68	2.45	2.29	2.18	2.09	2.02	1.96	1.91	1.83	1.75	1.66	1.61	1.55
∞	3.84	3.00	2.60	2.37	2.21	2.10	2.01	1.94	1.88	1.83	1.75	1.67	1.57	1.52	1.46

Source : John E. Freund, Modern Elementary Statistics, (New Jersey: Prentice-Hall,1988), p.515.

Appendix H:

Minitab Command File Constructed for Data Analysis of This Study.

```
NOECHO
NOTE (K1)THICKNESS    INCH
NOTE (K4)GRIP SEPERATION - INCH
NOTE (K5)CHART SPEED    MM./MIN.
NOTE (K6)CROSS HEAD SPEED - MM./MIN.
LET K2=K5/25.4
LET K3=K6/25.4
LET C4=C2/0.454
LET C5=C3/25.4
LET C6=C4/(1*K1)
LET C7=(C5*K3*100)/(K3*K4)
LET C8=(C5*K3)/(K2*K4)
MEAN C4 K8
MEAN C6 K11
MEAN C7 K9
MEAN C8 K12
LET K10=K8/(1*K1)
LET K13=K11/K12
NAME C1='CODE' C2='LDBK-KG'
NAME C3='CHMV-MM' C4='LDBK-LB' C5='CHMV-IN'
NAME C6='TENSIBK' C7='ELONG%'
NOTE TENSILE STRGH. DATA FOR MAT. NO.8 PS (TD) :
PRINT C1-C7
NOTE AVERAGE TENSILE STRENGTHS AT BREAK (PSI) IS
PRINT K10
NOTE AVERAGE ELONGATION AT BREAK (%) IS
PRINT K9
NOTE STRESS IS
PRINT K11
NOTE STRAIN IS
PRINT K12
NOTE AVERAGE MODULUS OF ELASTICITY IS
PRINT K13
ECHO
END
```

```
NOECHO
NOTE MATERIAL NO.8 PS (TD)
PRINT C1-C7
NOTE
NOTE MATERIAL NO.8 PS (TD)
ONEWAY AOV ON DATA IN 'TENSIBK' SUBSCRIPTS IN 'CODE'
ONEWAY AOV ON DATA IN 'ELONG%' SUBSCRIPTS IN 'CODE'
NOTE
NOTE TENSIBK   = TENSILE STRENGTHS AT BREAK (PSI)
NOTE ELONG%    = AVERAGE ELONGATION AT BREAK (%)
NOTE
NOTE CODE  800= MAT. NO.8 , IRRADIATED  0.0 MRAD.
NOTE CODE  825= MAT. NO.8 , IRRADIATED  2.5 MRAD.
NOTE CODE  850= MAT. NO.8 , IRRADIATED  5.0 MRAD.
NOTE CODE  870= MAT. NO.8 , IRRADIATED  7.0 MRAD.
NOTE CODE 8100= MAT. NO.8 , IRRADIATED 10.0 MRAD.
END
```

```
PRINT C1 C10 C6 C7
PLOT C6 VS C10
PLOT C7 VS C10
PLOT C7 VS C6
CORRELATION C10 C6 C7
END
```

Appendix I:

Minitab Analysis Result - from the previous command file.

(One example of the 16 data resulted from eight film samples.)

WORKSHEET SAVED 3/ 6/1989

Worksheet retrieved from file: IN8INW.MTW
MATERIAL NO.8 PS (TD)

ROW	CODE	I.DBK-KG	CHMV-MM	I.DBK-I.B	CHMV-IN	TENSIBK	ELONG%
1	800	13.50	12	29.7357	0.47244	3303.97	23.6220
2	800	13.80	13	30.3965	0.51181	3377.39	25.5905
3	800	14.20	29	31.2775	1.14173	3475.28	57.0866
4	800	14.30	25	31.4978	0.98425	3499.76	49.2126
5	800	14.80	30	32.5991	1.18110	3622.12	59.0551
6	800	14.00	26	30.8370	1.02362	3426.33	51.1811
7	800	14.30	14	31.4978	0.55118	3499.76	27.5591
8	800	14.20	15	31.2775	0.59055	3475.28	29.5276
9	800	13.70	14	30.1762	0.55118	3352.91	27.5591
10	800	13.90	15	30.6167	0.59055	3401.86	29.5276
11	800	13.40	21	29.5154	0.82677	3279.49	41.3386
12	800	14.60	29	32.1586	1.14173	3573.18	57.0866
13	800	14.10	26	31.0573	1.02362	3450.81	51.1811
14	800	13.90	14	30.6167	0.55118	3401.86	27.5591
15	800	13.90	15	30.6167	0.59055	3401.86	29.5276
16	800	13.50	21	29.7357	0.82677	3303.97	41.3386
17	800	13.20	10	29.0749	0.39370	3230.54	19.6850
18	800	13.80	17	30.3965	0.66929	3377.39	33.4646
19	800	14.00	25	30.8370	0.98425	3426.33	49.2126
20	800	13.90	26	30.6167	1.02362	3401.86	51.1811
21	825	13.70	42	30.1762	1.65354	3352.91	66.1417
22	825	13.10	34	28.8546	1.33858	3206.07	53.5433
23	825	13.40	37	29.5154	1.45669	3279.49	58.2677
24	825	12.40	26	27.3128	1.02362	3034.75	40.9449
25	825	13.00	28	28.6344	1.10236	3181.60	44.0945
26	825	13.50	32	29.7357	1.25984	3303.97	50.3937
27	825	13.00	25	28.6344	0.98425	3181.60	39.3701
28	825	13.40	33	29.5154	1.29921	3279.49	51.9685
29	825	12.90	30	28.4141	1.18110	3157.12	47.2441
30	825	12.50	24	27.5330	0.94488	3059.23	37.7953
31	825	13.50	31	29.7357	1.22047	3303.97	48.8189
32	825	13.20	28	29.0749	1.10236	3230.54	44.0945
33	825	13.50	33	29.7357	1.29921	3303.97	51.9685
34	825	13.70	28	30.1762	1.10236	3352.91	44.0945
35	825	13.30	41	29.2952	1.61417	3255.02	64.5669
36	825	13.70	32	30.1762	1.25984	3352.91	50.3937
37	825	12.60	35	27.7533	1.37795	3083.70	55.1181
38	825	13.00	32	28.6344	1.25984	3181.60	50.3937
39	825	13.50	32	29.7357	1.25984	3303.97	50.3937
40	825	13.00	23	28.6344	0.90551	3181.60	36.2205
41	850	13.25	34	29.1850	1.33858	3242.78	53.5433
42	850	12.50	32	27.5330	1.25984	3059.23	50.3937
43	850	12.75	26	28.0837	1.02362	3120.41	40.9449
44	850	12.25	28	26.9824	1.10236	2998.04	44.0945
45	850	13.25	35	29.1850	1.37795	3242.78	55.1181
46	850	13.00	38	28.6344	1.49606	3181.60	59.8425
47	850	13.25	39	29.1850	1.53543	3242.78	61.4173
48	850	12.75	32	28.0837	1.25984	3120.41	50.3937
49	850	13.25	40	29.1850	1.57480	3242.78	62.9921
50	850	12.50	30	27.5330	1.18110	3059.23	47.2441
51	850	13.75	42	30.2863	1.65354	3365.15	66.1417
52	850	13.25	31	29.1850	1.22047	3242.78	48.8189
53	850	13.00	22	28.6344	0.86614	3181.60	34.6457
54	850	13.50	30	29.7357	1.18110	3303.97	47.2441
55	850	13.00	24	28.6344	0.94488	3181.60	37.7953
56	850	13.25	30	29.1850	1.18110	3242.78	47.2441
57	850	13.25	27	29.1850	1.06299	3242.78	42.5197
58	850	13.00	29	28.6344	1.14173	3181.60	45.6693
59	850	13.50	32	29.7357	1.25984	3303.97	50.3937
60	850	13.00	24	28.6344	0.94488	3181.60	37.7953
61	870	13.20	21	29.0749	0.82677	3230.54	33.0709
62	870	14.40	35	31.7181	1.37795	3524.23	55.1181
63	870	14.20	34	31.2775	1.33858	3475.28	53.5433
64	870	13.70	30	30.1762	1.18110	3352.91	47.2441
65	870	14.00	35	30.8370	1.37795	3426.33	55.1181
66	870	13.20	32	29.0749	1.25984	3230.54	50.3937
67	870	13.50	37	29.7357	1.45669	3303.97	58.2677
68	870	14.40	42	31.7181	1.65354	3524.23	66.1417
69	870	14.10	37	31.0573	1.45669	3450.81	58.2677
70	870	14.40	39	31.7181	1.53543	3524.23	61.4173
71	870	14.20	39	31.2775	1.53543	3475.28	61.4173
72	870	13.60	35	29.9559	1.37795	3328.44	55.1181
73	870	13.60	34	29.9559	1.33858	3328.44	53.5433
74	870	13.80	39	30.3965	1.53543	3377.39	61.4173
75	870	13.70	39	30.1762	1.53543	3352.91	61.4173
76	870	13.30	22	29.2952	0.86614	3255.02	34.6457
77	870	13.80	39	30.3965	1.53543	3377.39	61.4173
78	870	14.40	32	31.7181	1.25984	3524.23	50.3937
79	870	13.30	36	29.2952	1.41732	3255.02	56.6929
80	870	12.90	20	28.4141	0.78740	3157.12	31.4961

81	8100	12.20	24	26.8722	0.94488	2985.81	37.7953
82	8100	11.90	31	26.2115	1.22047	2912.38	48.8189
83	8100	12.90	40	28.4141	1.57480	3157.12	62.9921
84	8100	12.20	34	26.8722	1.33858	2985.81	53.5433
85	8100	12.90	38	28.4141	1.49606	3157.12	59.8425
86	8100	11.20	22	24.6696	0.86614	2741.07	34.6457
87	8100	11.60	27	25.5507	1.06299	2838.96	42.5197
88	8100	11.50	28	25.3304	1.10236	2814.49	44.0945
89	8100	13.00	39	28.6344	1.53543	3181.60	61.4173
90	8100	12.20	34	26.8722	1.33858	2985.81	53.5433
91	8100	11.70	27	25.7709	1.06299	2863.44	42.5197
92	8100	12.80	32	28.1938	1.25984	3132.65	50.3937
93	8100	12.40	36	27.3128	1.41732	3034.75	56.6929
94	8100	11.60	22	25.5507	0.86614	2838.96	34.6457
95	8100	13.10	32	28.8546	1.25984	3206.07	50.3937
96	8100	11.80	29	25.9912	1.14173	2887.91	45.6693
97	8100	13.00	29	28.6344	1.14173	3181.60	45.6693
98	8100	12.00	24	26.4317	0.94488	2936.86	37.7953
99	8100	11.80	29	25.9912	1.14173	2887.91	45.6693
100	8100	11.80	24	25.9912	0.94488	2887.91	37.7953

MATERIAL NO.8 PS (TD)

ANALYSIS OF VARIANCE ON TENSIBK

SOURCE	DF	SS	MS	F	p
CODE	4	2345671	586418	48.63	0.000
ERROR	95	1145612	12059		
TOTAL	99	3491283			

LEVEL	N	MEAN	STDEV	INDIVIDUAL 95 PCT CI'S FOR MEAN BASED ON POOLED STDEV
800	20	3414.1	96.1	(---*--)
825	20	3229.3	96.4	(--*---)
850	20	3196.9	90.7	(--*--)
870	20	3373.7	113.8	(--*--)
8100	20	2980.9	143.5	(---*--)
POOLED STDEV =		109.8		3000 3150 3300 3450

ANALYSIS OF VARIANCE ON ELONGX

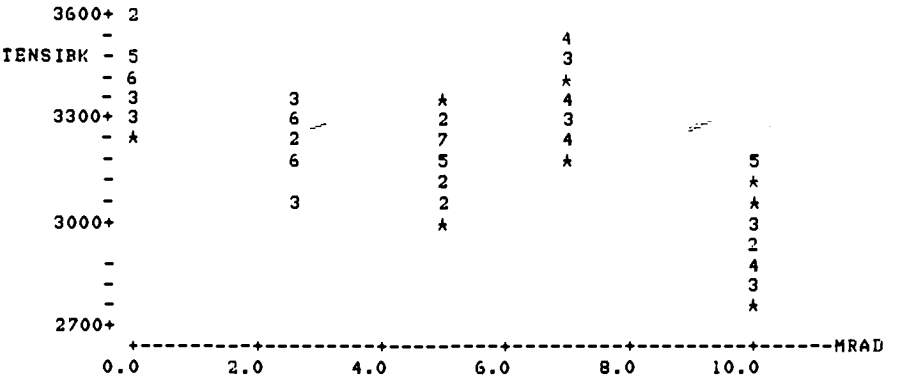
SOURCE	DF	SS	MS	F	p
CODE	4	2215.6	553.9	5.75	0.000
ERROR	95	9158.5	96.4		
TOTAL	99	11374.1			

LEVEL	N	MEAN	STDEV	INDIVIDUAL 95 PCT CI'S FOR MEAN BASED ON POOLED STDEV
800	20	39.075	12.984	(-----*-----)
825	20	49.291	8.032	(-----*------)
850	20	49.213	8.684	(-----*------)
870	20	53.307	9.871	(-----*-----)
8100	20	47.323	8.723	(------*-----)
POOLED STDEV =		9.819		35.0 42.0 49.0 56.0

TENSIBK = TENSILE STRENGTHS AT BREAK (PSI)
ELONGX = AVERAGE ELONGATION AT BREAK (%)

CODE 800= MAT. NO.8 , IRRADIATED 0.0 MRAD.
CODE 825= MAT. NO.8 , IRRADIATED 2.5 MRAD.
CODE 850= MAT. NO.8 , IRRADIATED 5.0 MRAD.
CODE 870= MAT. NO.8 , IRRADIATED 7.0 MRAD.
CODE 8100= MAT. NO.8 , IRRADIATED 10.0 MRAD.

```
MTB > PLOT C6 VS C10
```

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MTB > PLOT C7 VS C10
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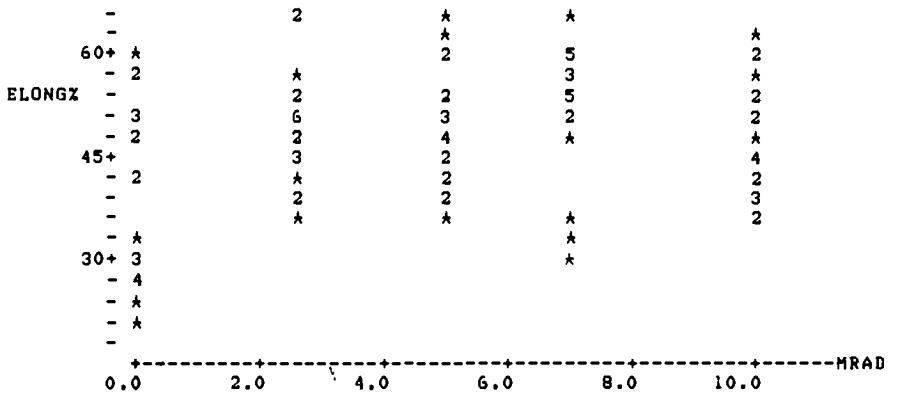


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MTB > PLOT C7 VS C6
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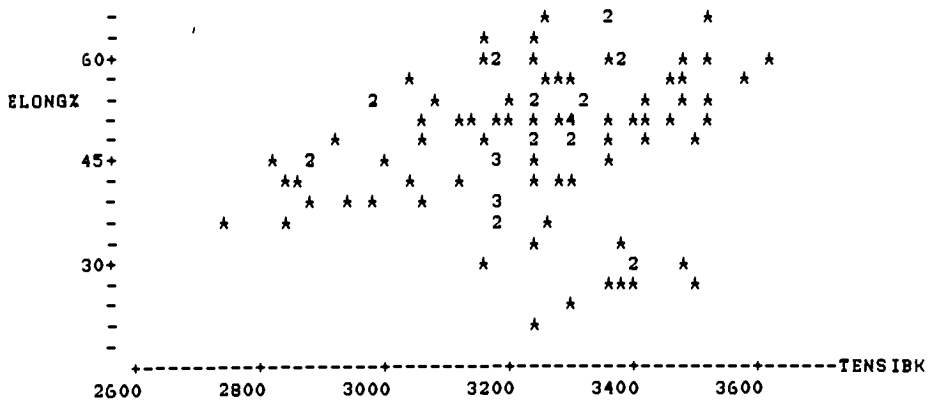


```
MTB > CORRELATION C10 C6 C7

            MRAD  TENSIBK
TENSIBK   -0.578
ELONGX     0.262    0.220

MTB > END
MTB > NOOUTFILE  (INSTCL)
```

Appendix J:

The Units of Radiation Dose and The Units of Radiation Processing.

The Units of Radiation Dose.

The amount of radiation received by material bombard by electrons is called a Gray (Gy). One Gray(Gy) equals the energy of one joule per kilogram of matter. The rad also appears as a unit of radiation dose.

1 Gy. = 100 rads.

10 kGy. = 1 Mrads. (1,000,000 rads.)

(kGy = kilogray, Mrads = megarads)

For electron beam process, the amount of energy used to describe radiation is called an electron volt (eV).

1 eV = The kinetic energy that a free electron in a vacum picks up when it accelerates in a field of one volt.

1 MeV = One millions of electron volts.

Source : Marc Sillard and Jim Wagner, "Pasteurizing with Electrons," Food Engineering International, March 1989, p.41.

The Units of Radiation Processing

1 rad. = 100 ergs/gram.

1 megarad = 10^6 rads = 10^8 ergs/gram = 10 joules/gram = 2.40 calories/gram

1 Gy. = 100 rads.

1 kiloGray = 10^5 rads = 10^7 ergs/gram = 1 joule/gram = 0.24 calories/gram

so 10 kGy. = 1 Mrad. = 1000 krads.

source : Judith N. Aaronson and Sam V. Nablo. " Electron Bean Sterilization - Its monitoring and control. " Paper presented at the Symposium on Applications and Advances in Aseptic technology, Aseptic Processing and Packaging, North Carolina State University, Raleigh, NC, November 10-14, 1986. p.11.